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INTERNATIONAL JOURNAL OF ADVANCED RESEARCH (IJAR)

Article DOI: 10.21474/IJAR01/12570
DOI URL: http://dx.doi.org/10.21474/IJAR01/12570

RESEARCH ARTICLE

A RANDOMIZED CONTROLLED TRIAL ON THE EFFICACY OF *VACHADI CHOORNA* IN SPEECH IMPAIRMENT IN CHILDREN UP TO 12 YEARS

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Manuscript Info

Manuscript History
Received: 10 January 2021
Final Accepted: 14 February 2021
Published: March 2021

Key words:-
Randomized Controlled Trial, Vachadi Choorna, Speech Impairment, Stuttering Severity Instrument, Malayalam Articulation Test

Abstract

Speech Impairment is the most common impairments presenting in early childhood (8-9%). It can make the children difficult to communicate with other people and often affects a child's quality of life.

Objective*:* The aim of the study was to assess the efficacy of *Vachadi Choorna* in speech impairment in children up to 12 years.

Experimental approach: The study was carried out as a Randomized Controlled Trial, with speech therapy as a control of which efficacy has been proved by earlier studies. Children with speech impairment satisfying the inclusion criteria were included in the study. The subjects were randomly distributed into the study and control groups using simple random sampling. Children in the study group received *Vachadi Choorna* in two divided doses for internal administration for 45 days while control group received speech therapy as per schedule fixed by Speech-Language pathologist for 45 days.

Findings: The graded responses in both groups were assessed after the treatment and after follow up, clinically and also by using a scale based on Stuttering Severity Instrument for stuttering and Malayalam Articulation Test for Articulation.

Discussion*:* Analysis of the data using the most appropriate statistical test showed that the trial drug and the speech therapy were effective in improving speech ($p<0.001$).

Conclusion*:* The effect of the trial drug in improving speech was significantly greater than that of control group ($p<0.05$). Thus the efficacy of the drug combination applied in the trial group and its superiority over the control therapy was proved.

Introduction:-

Children with speech difficulties may have trouble in school or with peers. Some children with speech difficulties may have severe communication problem and problem with educational status, including reading, and writing. The overall estimate for speech and language disorders is widely agreed to be 5% of school-aged children[1]. The

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incidence of elementary school children who exhibit delayed phonological (articulation) development is 2% to 3%, although the percentage decreases steadily with age[ii]. Speech disorders though not properly mentioned in our classics can be understood by applying the basic principles of Ayurveda based on which the entire system was designed. So a scientific study on Speech Impairment in Ayurvedic point of view and a possible solution for this momentous problem using Ayurvedic principle was intended.

Shabda (speech) is an audible manifestation of *Bhasa* (language). It is a complex motor mechanism. Speech and language are having independent entity. Language is the faculty of *buddhi* (cognition) while speech is produced by external sense organs. Tongue is the main organ for producing speech[1]. With the help of mind (*manas*) and sense organ of hearing (*sravana indriya*) reception of speech takes place and after analysis by speech centers in brain expression of speech takes place with the help of organs of speech production (*vag indriya*). For completing speech mechanism, sense of reception needs an intact sense organ. Centers in the brain are receiving such senses and after analysis they are stimulating the sense organs for action (*karma indriyas*) with the help of mind and soul (*Atman*) to get proper action. The sense organs for speech, by the influence of higher centers, help in articulation, and do sound production. Sound is the quality of space (*Akash*) and it is perceived by sense organs for hearing. That sound is basically of two types. They are Language (*Verna Lakshana Sabdha*) and Phonation (*Dhwani Lakshana Sahabda*)[iii]. The stimuli are perceived by audio receptive centre construct the idea and audio motor centre helps to articulate. *Vak Vikruti* i.e. *Mookatwam* (muteness), *Minminatwam* (unclear and speech of nasal origin) and *Gadgadatwakatvam* (unintelligible speech) are explained in eighty types of vata vitiated disordersiv. These are also mentioned as features of disorders due to obstruction of channels[v]. According to *Susrutha*, *vata* with *kapha* obstructs the *Sabdavahini Dhaminies* and results into muteness, speech of nasal origin and unintelligible speech[vi].

Materials and Methods:-

Materials:

Vachadi Churna (an Ayurvedic powder formulation of medicinal plant parts) mentioned in Ashtanga Hridaya in the context of child care (Balopacharaniya) was used as study drug for internal administrationvii. The ingredients of Vachadi Churna were dried roots of Vacha (Acorus calamus), Yasti-madhu (Glycyrrhiza glabra), Kustha (Saussurea lapa), Fruits of Pathaya (Terminalia chebula), Nagar (Zingiber officinale), Dipyaka (Trachispermum roxburghianum), Kanaa (Piper longam), seeds of Jiraka (Cuminum cyminum) and Saindhava in equal quantity. The identity, purity, and content of medicinal plant materials of raw drugs were tested and prepared in the Pharmacy Department, Govt: Ayurveda College, Thiruvananthapuram.

Method:-

Experimental, Therapeutic, Randomized Controlled Trial. Source Population was children with clinical features of speech impairment with age limit of 0 to 12 years attending the outpatient unit of Department of Kaumarabhrithya, Govt. Ayurveda College Hospital for Women and Children, Poojappura, Thiruvananthapuram and National Institute of Speech and Hearing, Thiruvananthapuram were the research population of the study. Simple Random sampling was followed in the study. The subjects were selected as per the selection criteria and randomly distributed to study and control groups respectively. For the random distribution of subjects, Table of Random Numbers was used. Total of 40 cases were recruited, 20 in the study group and 20 in the control group. Sampling element was children of 0 to 12 years affected with Speech Impairment. Children of 0-12 year age with clinical features of Speech Impairment attending the O.P.D. of the department of Kaumarabhrithya at Govt. Ayurveda college Hospital for Women and Children, Poojappura, Thiruvananthapuram and National Institute of Speech and Hearing, Thiruvananthapuram were sampling fractions. Outpatient section of the department of Kaumarabhrithya at Govt. Ayurveda college Hospital for Women and Children, Poojappura, Thiruvananthapuram and National Institute of Speech and Hearing, Thiruvananthapuram were selected as the research setting.

Inclusion Criteria:

Children of 0 to 12 years presenting with clinical manifestations of speech impairment were included in the study**.**

Exclusion Criteria:

Children suffering from Brain damage, other systemic disorders and those who are not willing to co-operate with the study were excluded from the study.

Technique of Data Collection:
As per the inclusion criteria, a specially formatted proforma was used to extract and record the extensive data from the caregivers. To ensure sufficient accuracy relevant data were collected with the help of proforma provided by National Institute of Speech and Hearing, Thiruvananthapuram under supervision of speech – Language Pathologist in the department of *Kaumarabhrithya* at Govt. Ayurveda college Hospital for Women and Children, Poojappura, Thiruvananthapuram.

Research technique and Tool:
A clinical proforma was designed to collect and record the information verbally reported by the parents and subjects after thorough interrogation. Here an assessment scale based on Stuttering Severity Instrument – 3rd editions, Malayalam Articulation Test and a scale for the clinical assessment of signs and symptoms were used as the tool for assessing the changes in the clinical manifestation of the disease (dependent variable).

Treatment Schedule:
Children of age group of 0 -12 years attending the outpatient unit of *Kaumarabhritya* department were screened for speech impairment using clinical parameters.

Intervention Group:
The children in the study group were received *Vachadi churna* in a varying dosage of 500mg to 2000mg per day depending on their age in two divided doses internally for 45 days (0-3 years:500mg; 3-6 years:1000mg; 6-9 years:1500mg and 9-12 years : 2000mg) mixed with plane *Ghrita.*

Comparator Group:
Children in the control group were received speech therapy – the intervention as control according to schedule fixed by Speech-Language pathologist for 45 days. The graded responses in both the study and the control groups were obtained after the treatment and after follow up, clinically and also by using a scale based on Stuttering Severity Instrument – 3rd editions and Malayalam Articulation Test. Follow up was done for one month after the treatment.

Assessment Criteria:
Both the groups were assessed before and after the study by observing Graded clinical signs and symptoms, Stuttering Severity Instrument – 3rd editions[viii], Malayalam Articulation Test. Malayalam Articulation Test (MAT) assesses articulation and phonology of Malayalam speaking preschool and school-age children[ix].There were no drop-outs from the trial group and the control group.

Data Analysis:
Data were consolidated by using statistical methods. The efficacy of the intervention was evaluated and conclusions were drawn by using statistical tests such as Mann Whitney Rank Sum Test, Paired‘t’ test and Student t test.

Observation, Analysis and Discussion:-

Forty (40) patients were selected for the clinical trial. All subjects completed the course of treatment. Selected treatment drug that include internal administration of *vachadi choorna* (an *Ayurvedic* formulation of medicinal plant parts) was given for trial group and speech therapy was advised for control group. Data was collected before treatment, after treatment and after follow up. All these data were statistically analyzed and discussed in detail and the outcome is presented below.

Description of the subjects and the disease:
Male subjects (55%) were more vulnerable in this study. This is in accordance with the fact produced by the National Institute on Deafness and Other Communication Disorders (NIDCD) that Boys are 3 times more likely to have speech disorders than girls[x]. The demographic data showed that in both groups, majority of subjects belonged to age group 2-4 years. In more recent work, Campbell et al. (2003) reported a prevalence of 15.6% for speech sound disorders in 3-year-old children in a large, diverse community sample[xi]. The lower prevalence rates at older ages are consistent with evidence that speech sound disorders may resolve over time[xii]. In this study, most of the subjects were not attending the school (30%). This may be because of ignorance and non acceptance of special school by parents for children with speech disorders. Here, majority of parents (95%) were highly educated and working in different sectors. The main cause behind speech disorders are negligence of children by parents. Negative / poor parent child interaction, punitive parent, inconsistency in parenting and difference of opinion in

parents could be chronic stressors to the child[xiii]. Studies showed that mothers did not treat their children differently on the basis of the speech symptom under non-achievement oriented conditions. Mothers were more negative toward the speech-symptom child[xiv]. Majority of subjects are having positive family history of speech impairment. Studies conducted on positive family history as a risk factor for speech disorders showed that children with positive family history were 7.71 times as likely to have a speech delay as a child without this factor[xv.] Here, majority of the subjects (70%) were having uneventful birth history. Damage sustained before, during, or shortly after birth (*i.e.,* perinatally) encompass the gamut of toxic, infectious, traumatic, nutritional, hormonal, and other damages that may hurt the growing fetus or young infant. Major and minor birth injury is not an infrequent factor. These factors also exhibit slow language development, lesser endowment in the brain area for language, inferior function in the highest brain areas of auditory performance without organic damage to the ears, slow maturation of motor function (including clumsiness and deviation from normal cerebral dominance), and other signs of delayed cerebral growth[xvi]. 50% subjects were having inadequate speech stimulation at home. It is in accordance with the fact that neurological, cognitive and emotional abilities of the child as well as verbal stimulation from the environment are crucial[xvii]. Eight out of 10 parents informed that stuttering interferes with schoolwork, and that their children avoid speaking situations. Census of NSA Members showed that Stuttering interferes with school/work (79%) and social/family (64%) interactions. Many feel embarrassed about stuttering (70%) and avoid speaking situations (82%).

Effect of therapy:

Effect of Therapy on Stuttering Severity Instrument – 3(SSI-3)**:**

Effectiveness of treatment on Frequency:

Effectiveness of treatment on frequency of job task (for readers):

The statistical evaluation of effectiveness of treatment on the frequency of job task reveals that the effect of the treatment was significant in both groups. In the Study group, mean ± SD value was 5.9 ± 1.4 before treatment which after treatment changed to 4.3 ± 1.3., and after follow up the mean value was 5.3 ± 1.1 and the mean score difference before and after treatment was 1.56. A highly significant change was noticed after treatment ($p<0.01$). The sustained action was not evident because increase in the mean score (from 4.3 to 5.3) was noticed during the follow up period. In the control group the effect of the treatment was also significant. The mean value before treatment was 5.3 ± 1.5 which changed to 4.6± 1.2 after treatment and after follow up the value was 4.8±1.7 and the mean score difference was 2.4. A significant change was noticed in this group after treatment also ($p<0.05$). The sustained action of the therapy was not evident because there was increase in the mean score from 4.6 to 4.8 during the follow up period. Thus both therapies were effective in this particular parameter.

Table 1:- Effectiveness of treatment on frequency of job task (for readers)

Group	Stage	Mean	SD	N	Mean Difference	Paired ' t'	p
Study	BT	5.9	1.4	9	1.56	3.78	
	AT	4.3	1.3	9			<0.01
	AFU	5.3	1.1	9			
Control	BT	5.3	1.5	9	0.78	2.4	<0.05
	AT	4.6	1.2	9			
	AFU	4.8	1.7	9			

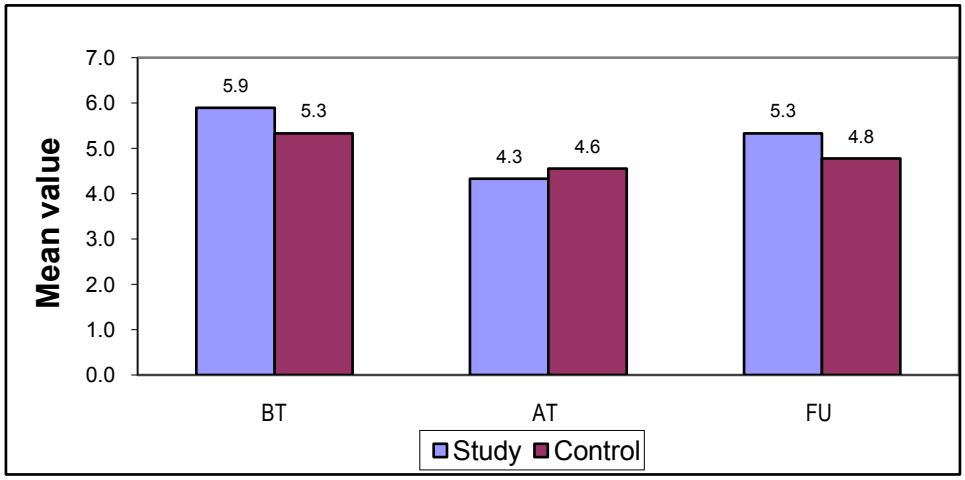


Figure 1:- Effectiveness of treatment on frequency of job task.

Table 2:- Comparison of effectiveness of frequency of job task (percentage change) based on treatment					
Group	Mean	SD	N	t	p
Study	25.8	20.2	9	1.38	>0.05
Control	13.4	18.1	9		

A comparison of effectiveness of frequency of job task between study and control groups did not show any significant difference between them ($p>0.05$). Thus, the treatment is helpful in improving the frequency of job task of the subjects, there may not be remarkable difference based on treatment in groups.

Effectiveness of treatment on frequency of reading task (for readers):

The statistical evaluation of effectiveness of treatment on the frequency of reading task reveals that the effect of the treatment was highly significant in both groups. In the Study group, mean ± SD value was 6.8 ± 1.2 before treatment which after treatment changed to 4.3 ± 1.2 and after follow up the mean value was 5.3 ± 0.9 and the mean score difference before and after treatment was 1.11. A highly significant change was noticed in this group after treatment ($p<0.01$). The sustained action was not evident because increase in the mean score (from 4.3 to 5.3) was noticed during the follow up period. In the control group the effect of the treatment was also highly significant. The mean value before treatment was 6.6 ± 1.8 which changed to 5.4± 2.1 after treatment and after follow up the value was 4.9±1.7 and the mean score difference was 2.44. A highly significant change was also noticed in this group ($p<0.001$) also. The sustained action of the therapy was evident because there was further decrease in the mean score from 5.4 to 4.9 during the follow up period. Thus both therapies were highly effective in this particular parameter but control therapy was more effective and had sustained action in this particular parameter.

Table 3:- Effectiveness of treatment on frequency of reading task (for readers)							
Group	Stage	Mean	SD	N	Mean Difference	Paired 't'	p
Study	BT	6.8	1.2	9	1.11	4.26	<0.01
	AT	4.3	1.2	9			
	AFU	5.3	0.9	9			
Control	BT	6.6	1.8	9	2.44	7.23	<0.001
	AT	5.4	2.1	9			
	AFU	4.9	1.7	9			

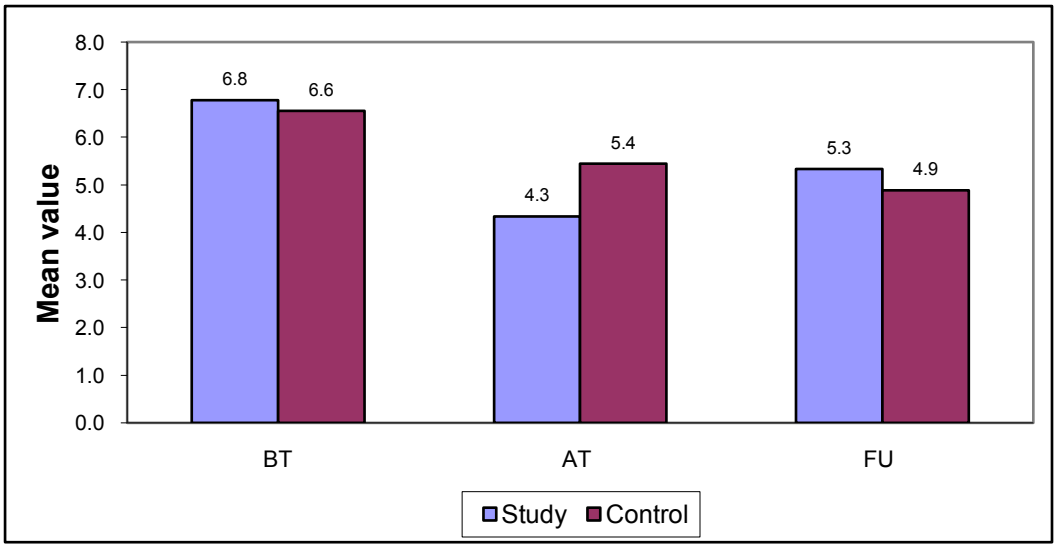


Figure 2:- Effectiveness of treatment on frequency of reading task

Table 4:- Comparison of effectiveness of frequency of reading task (percentage change) based on treatment					
Group	Mean	SD	N	t	p
Study	36.2	14.7	9	2.41	<0.05
Control	19.3	15.1	9		

A comparison of effectiveness of frequency of reading task between study and control groups depicted significant difference between them ($p<0.05$). This means that the trial drug was more helpful in this particular parameter.

Effectiveness of treatment on frequency of picture task (for non-readers):

The statistical evaluation of effectiveness of treatment on the frequency of picture task reveals that the effect of the treatment was not significant in both groups. In the Study group, mean ± SD value was 9.0 ± 1.4 before treatment which after treatment changed to 5.0 ± 1.4 and after follow up the mean value was 6.0 ± 0.0. No significant change was noticed here ($p>0.05$). The sustained action was not evident because increase in the mean score (from 5.0 to 6.0) was noticed during the follow up period. In the control group, mean value before treatment was 10.0 ± 2.0 which changed to 6.7± 2.3 after treatment and after follow up the value was 6.0±2.0. Here also no significant change was noticed ($p>0.05$). The sustained action of the therapy was evident because there was further decrease in the mean score from 6.7 to 6.0 during the follow up period. Thus both therapies were not statically significant in this particular parameter.

Table 5:-Effectiveness of treatment on frequency of picture task							
Group	Stage	Mean	SD	N	Mean Difference	Paired 't'	p
Study	BT	9.0	1.4	2	3.33	3.1	>0.05
	AT	5.0	1.4	2			
	AFU	6.0	0.0	2			
Control	BT	10.0	2.0	3	3.00	3	>0.05
	AT	6.7	2.3	3			
	AFU	6.0	2.0	3			

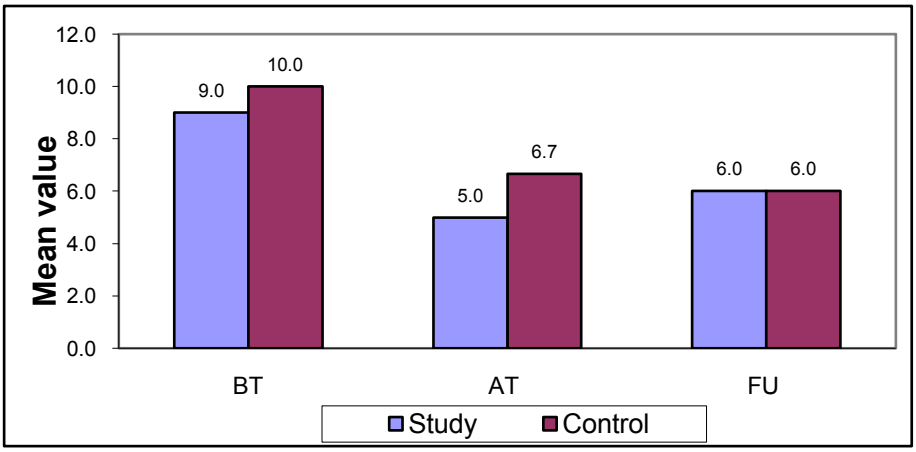


Figure 3:- Effectiveness of treatment on frequency of picture task

Table 6: ***Comparison of effectiveness of frequency of picture task (percentage change) based on treatment***					
Group	Mean	SD	N	t	p
Study	45.0	7.1	2	0.89	>0.05
Control	34.4	15.0	3		

A comparison of effectiveness of frequency of picture task between study and control groups did not show any significant difference between them (p>0.05). This means that this difference is considered to be not statically significant.

Effectiveness of treatment on overall frequency:

The statistical evaluation of effectiveness of treatment on overall frequency reveals that the effect of the treatment was highly significant in both groups. In the study group, mean ± SD value was 12.0 ± 2.7 which changed to 8.00 ± 2.7 after treatment and after follow up the value was 9.8 ± 2.4 which were highly significant(p<0.001). The sustained action was not evident because increase in the mean score (from 8.0 to 9.8) was noticed during the follow up period. In the control group, mean ± SD value before treatment was 11.4 ± 2.9 before treatment which after treatment changed to 9.2 ± 3.3, and after follow up the mean duration was 8.8 ± 3.4 which is also highly significant(p<0.001). The sustained action of the therapy was evident because there was further decrease in the mean score from 9.2 to 8.8 during the follow up period. Thus both therapies were highly significant in this particular parameter.

Table 7:-Effectiveness of treatment on overall frequency

Group	Stage	Mean	SD	N	Mean Difference	Paired 't'	p
Study	BT	12.0	2.7	11	4.0	6.81	<0.001
	AT	8.0	2.7	11			
	AFU	9.8	2.4	11			
Control	BT	11.4	2.9	12	2.3	6.41	<0.001
	AT	9.2	3.3	12			
	AFU	8.8	3.4	12			

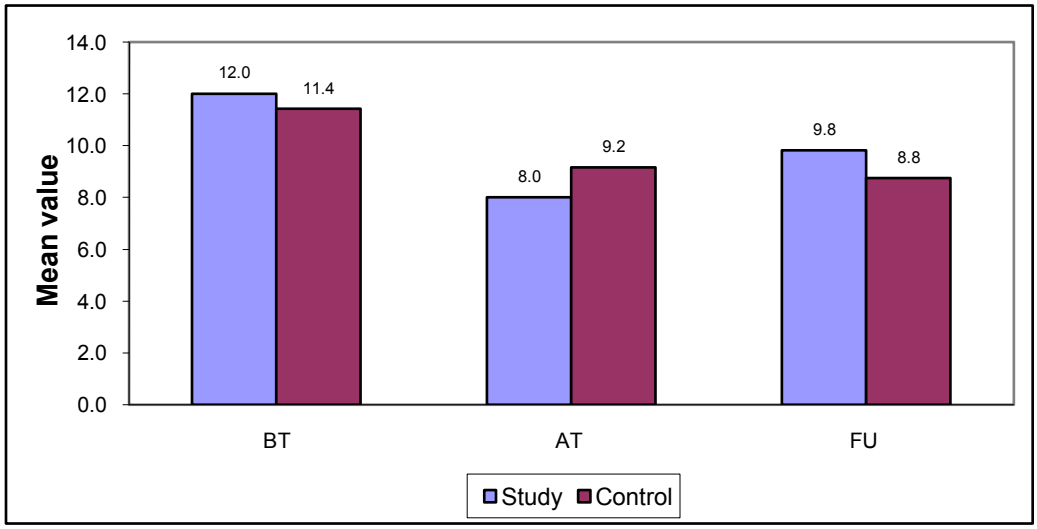


Figure 4:- Effectiveness of treatment on overall frequency

Table 8:- Comparison of effectiveness of overall frequency (percentage change) based on treatment

Group	Mean	SD	N	t	p
Study	27.3	28.2	11	2.24	<0.05
Control	6.3	15.5	12		

While comparing effectiveness of overall frequency based on treatment between two groups, there was a statistically significant difference noticed between the effect of therapies in Trial and control group (t = 2.248; <0.05). This shows that treatment given to study group is significantly effective than that of control group (significant at 0.05 level).

Effectiveness of treatment on duration:

The statistical evaluation of effectiveness of treatment on duration reveals that the effect of the treatment was significant in study groups. In the Study group, mean ± SD value before treatment was 2.3 ± 1.0 which changed to 1.5 ± 0.5 after treatment and after follow up the value was 1.7± 0.8. There was significant change noticed after treatment ($p<0.05$). The sustained action was not evident because increase in the mean score (from 1.5 to 1.7) was noticed during the follow up period. In the control group, mean ± SD value before treatment was 2.2 ± 0.9 before treatment which after treatment changed to 2.0 ± 0.9, and after follow up the mean duration was 1.4 ± 0.8. Here no significant change was noticed after treatment ($p>0.05$). The sustained action of the therapy was evident because there was further decrease in the mean score from 2.0 to 1.4 during the follow up period. Thus trial drug was statically significant in this particular parameter (significant at 0.05 levels).

Table 9:- Effectiveness of treatment on duration

Group	Stage	Mean	SD	N	Mean Difference	Paired 't'	P
Study	BT	2.3	1.0	11	0.82	3.11	<0.05
	AT	1.5	0.5	11			
	AFU	1.7	0.8	11			
Control	BT	2.2	0.9	12	0.17	1.48	>0.05
	AT	2.0	0.9	12			
	AFU	1.4	0.8	12			

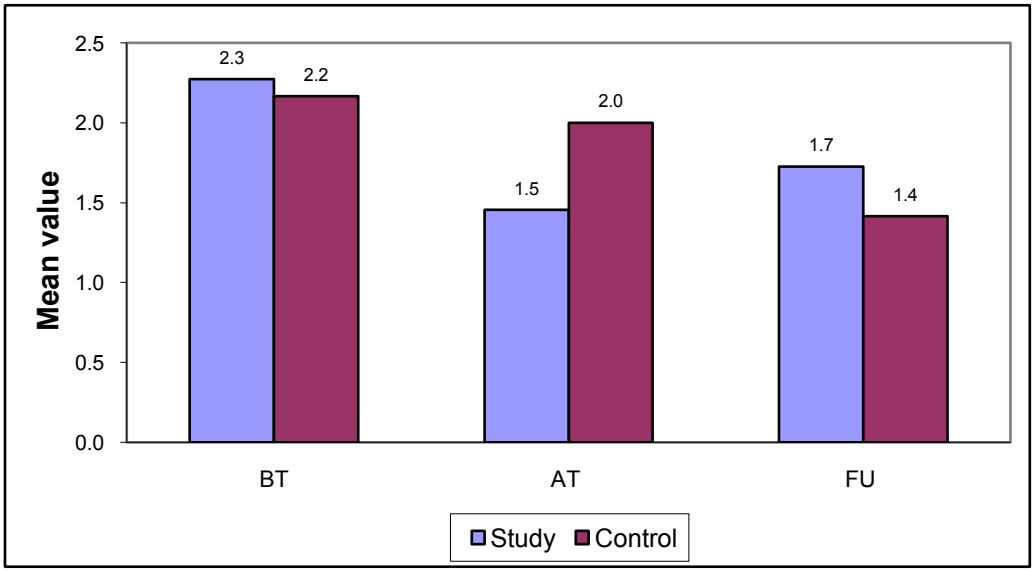


Figure 5:-Effectiveness of treatment on duration.

Table 10: ***Comparison of effectiveness of duration (percentage change) based on treatment***

Group	Mean	SD	N	t	p
Study	33.9	16.0	11	1.99	<0.05
Control	21.4	15.1	12		

While comparing effectiveness of duration based on treatment, there is a statistically significant difference noticed between the effect of therapies in Trial and control group. This shows the treatment given to study group is significantly effective than that of control group (significant at 0.05 level).

Effectiveness of treatment on overall physical concomitants:

The statistical evaluation of effectiveness of treatment on overall physical concomitants shows that the effect of the treatment was significant in both groups. In the Study group, mean ± SD value was 9.1 ± 4.0 before treatment which

after treatment changed to 3.5 ± 2.3., and after follow up the mean value of overall physical concomitants was 7.7 ± 3.2 which is significant and the mean score difference before and after treatment was 5.5. A highly significant change was noticed after treatment (p<0.001). The sustained action was not evident because of increase in the mean score from 3.5 to 7.7 during the follow up period. In the control group the effect of the treatment was also significant. The mean value of overall physical concomitants was 7.9 ± 3.8 which changed to 5.0± 3.8 after treatment and after follow up the value was 4.3 ± 4.5 and the mean score difference was 2.9. A significant change after treatment was noticed in this group (p>0.000) also. The sustained action was evident from the decrease in the mean score from 5.0 to 4.3 during the follow up period, so both therapies were effective in this particular parameter.

Table 11:- Effectiveness of treatment on overall physical concomitants

Group	Stage	Mean	SD	N	Mean Difference	Paired 't'	p
Study	BT	9.1	4.0	11	5.5	7.34	<0.001
	AT	3.5	2.3	11			
	AFU	7.7	3.2	11			
Control	BT	7.9	3.8	12	2.9	6.46	<0.001
	AT	5.0	3.8	12			
	AFU	4.3	4.5	12			

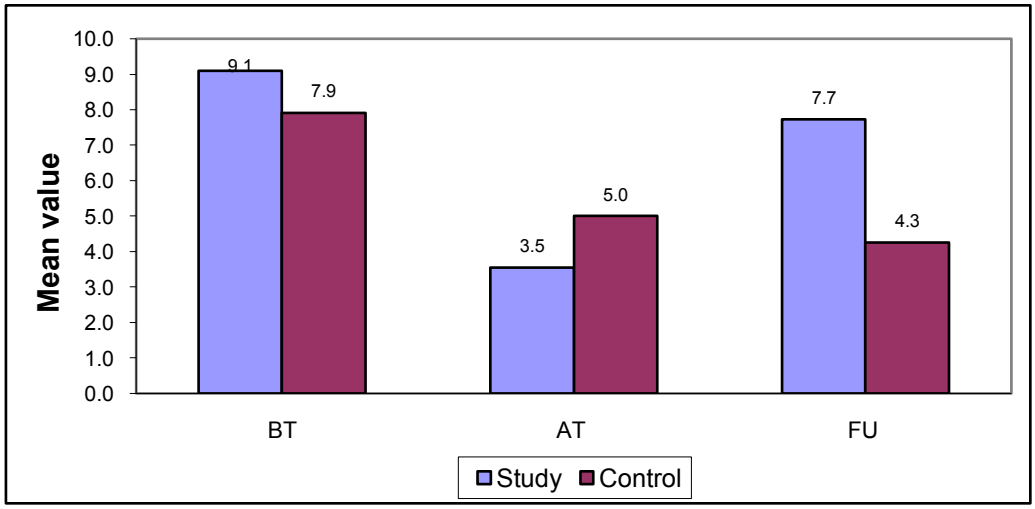


Figure 6:- Effectiveness of treatment on overall physical concomitants.

Table 12: ***Comparison of effectiveness of overall physical concomitants (percentage change) based on treatment***

Group	Mean	SD	N	t	p
Study	63.4	20.7	11	2.42	<0.05
Control	41.6	22.4	12		

While comparing effectiveness of overall physical concomitants based on treatment, there is a statistically significant difference noticed between the effect of therapies in Trial and control group (<0.05). This shows the treatment given to study group is significantly effective than that of control group (significant at 0.05 level).

Distribution of overall score at different stages under the treatment:

In study group, before treatment 0.0% children were having very mild stuttering, 27.3% mild, 27.3% moderate, 27.3% severe and 18.2% were having very severe stuttering. After treatment 18.2% children were having very mild stuttering, 45.5% mild, 36.4% moderate, 0.0% severe and 0.0% were having very severe stuttering. Thus shifting of severity was observed after treatment. After follow up very severe and very mild stuttering children were absent, 36.4% children showed moderate to severe stuttering and 27.3% showed mild stuttering. In the control group, before treatment 0.0% children were having very mild stuttering, 33.3% mild, 25.0% moderate, 25.0% severe and 16.7% were having very severe stuttering. After treatment 00.0% children were having very mild stuttering, 58.3% mild, 16.4% moderate, 25.0% severe and 0.0% were having very severe stuttering. Thus shifting of severity was observed

after treatment. After follow up severe stuttering children were absent, 50.0% children showed mild, 25% moderate, 8.3% very severe stuttering and 16.7% showed very mild stuttering.

Table 13:-Distribution of overall score at different stages under the treatment

Group	Overall score	BT		AT		FU	
		Count	%	Count	%	Count	%
Study	Very mild	0	0.0	2	18.2	0	0.0
	Mild	3	27.3	5	45.5	3	27.3
	Moderate	3	27.3	4	36.4	4	36.4
	Severe	3	27.3	0	0.0	4	36.4
	Very Severe	2	18.2	0	0.0	0	0.0
Control	Very mild	0	0.0	0	0.0	2	16.7
	Mild	4	33.3	7	58.3	6	50.0
	Moderate	3	25.0	2	16.7	3	25.0
	Severe	3	25.0	3	25.0	0	0.0
	Very Severe	2	16.7	0	0.0	1	8.3

Effectiveness of treatment on overall stuttering score:

The mean ± SD before treatment was 23.4±7.4 and changed to 13.0±5.0 and 19.3 ± 5.5 after treatment and after follow up respectively and the mean score difference before and after treatment was 10.4. A highly significant change was noticed after treatment ($p<0.001$). During follow up a further increase in the mean was seen. Thus action of the trial drug was not sustained. In the control group the mean ± SD before treatment was 21.5 ±7.4 which was changed to 16.2 ± 7.5 and 14.4 ± 8.3 after treatment and after follow up respectively and the mean score difference before and after treatment was 5.3. Thus, a highly significant change was noticed after treatment ($p<0.001$). But the result was not as effective as the trial drug.

Table 14:- Effectiveness of treatment on overall stuttering score

Group	Stage	Mean	SD	N	Mean Difference	Paired t	p
Study	BT	23.4	7.4	11	10.4	7.16	<0.001
	AT	13.0	5.0	11			
	AFU	19.3	5.5	11			
Control	BT	21.5	7.4	12	5.3	8.97	<0.001
	AT	16.2	7.5	12			
	AFU	14.4	8.3	12			

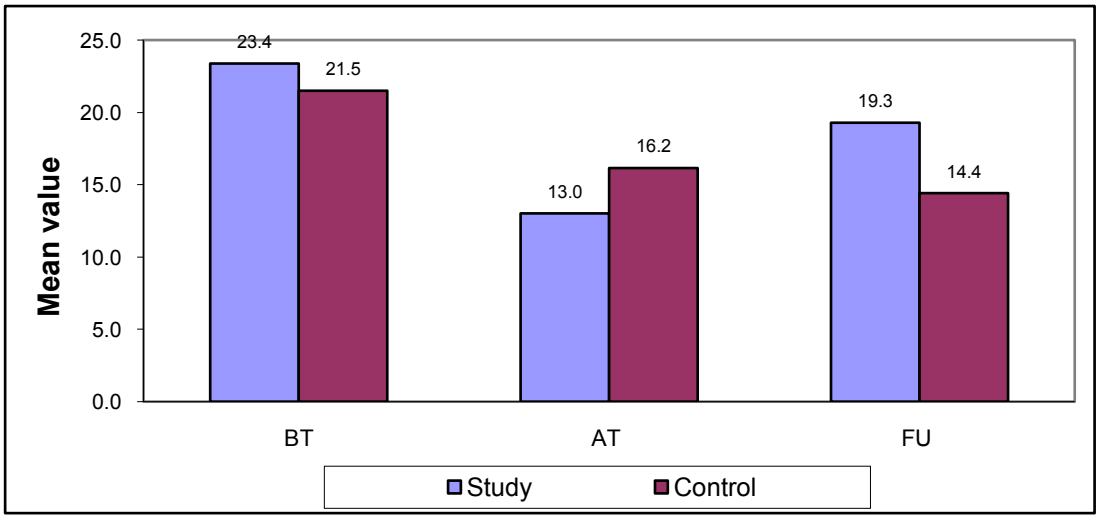


Figure 7:- Effectiveness of treatment on overall score.

Table 15: ***Comparison of effectiveness of overall score (percentage change) based on treatment***

Group	Mean	SD	N	t	p

Study	44.5	16.1	11	2.78	<0.05
Control	26.9	14.2	12		

While comparing between groups the study group is more significant than control group ($t = 2.78$; $p<0.05$). From this, we can infer that trial drug was more effective in managing stuttering. Therefore the ability of the trial drug in managing stuttering in children was proved.

Effectiveness of treatment on frequency of job task (for readers) showed that treatment given to trial group provided more relief ($p<0.01$) than the control therapy ($p<0.05$). Both were statistically significant. A comparison of effectiveness of treatment did not show any significant difference between them ($p>0.05$). Thus it is observed from statistical analysis that both the treatments have significant effect in managing the frequency of job task of the subjects and the treatment drug used in the trial group was significantly more effective than that of the control therapy. Effectiveness of treatments on frequency of reading task showed that treatment given to both groups was statistically highly significant. But, treatment given trial group provided less relief ($p<0.01$) than the control therapy ($p<0.001$). A comparison of effectiveness of treatment between groups showed significant difference between them ($p<0.05$). After follow up period, effect was sustained in control group. Thus it is observed from statistical analysis that both the treatments have highly significant effect in managing the frequency of reading task of the subjects and the treatment modality used in the trial group was significantly more effective than that of the control group.

Effectiveness of treatment on frequency of picture task (for non-readers) showed that treatment given to both group had no statistically significant effect ($p>0.05$). A comparison of effectiveness of treatment between groups did not showed significant difference between them ($p>0.05$). Thus it is observed from statistical analysis that both the treatments have no significant effect in managing the frequency of picture task of the subjects. Effectiveness of treatments on overall frequency showed that treatment given to both groups was statistically highly significant. Treatment given trial group provided more relief than the control therapy. Mean Difference in trial group was 4.0 and in control therapy, it was 2.3. A comparison of effectiveness of treatment between groups showed significant difference between them ($p<0.05$). Thus it is observed from statistical analysis that both the treatments have highly significant effect in managing overall frequency subjects and the drug combination used in the trial group was significantly more effective than that of the control group. Effectiveness of treatment on duration showed that treatment given to trial group provided more relief ($p<0.05$) than the control therapy ($p>0.05$). A comparison of effectiveness of treatment shows significant difference between them ($p<0.05$). Thus it is observed from statistical analysis that treatment used in the trial group was significantly more effective than that of the control group. Effectiveness of treatments on overall physical concomitants showed that treatment given to both groups was statistically highly significant. But, treatment given trial group provided more relief than the control therapy. Mean Difference in trial group was 5.5 and in control therapy, it was 2.9. A comparison of effectiveness of treatment between groups showed significant difference between them ($p<0.05$). Thus it is observed from statistical analysis that both the treatments have highly significant effect in managing overall physical concomitants of the subjects and the treatment used in the trial group was significantly more effective than that of the control group. Effectiveness of treatments on overall stuttering score showed that selected treatment drug provided more relief compared to control therapy after treatment. Mean difference in trial group was 10.4 and in control therapy, it was 5.3. Both were statistically highly significant ($p<0.001$). The relief was maintained in case of control group; while it reduced to in case of trial group after follow up period. Comparison between both groups was also statistically significant ($P<0.05$) after treatment. Thus it was observed from statistical analysis that both the treatments have highly significant effect in the management of stuttering disorder on Stuttering Severity Instrument – 3 and the treatment drug used in the trial group was significantly more effective than the therapy used in the control group.

Effect of Therapy on Articulations disorder:

Table 16:-Effectiveness of treatment on percentage of consonants correct under different treatment

Group	Severity	BT N (%)	AT N (%)	FU N (%)
Study	Mild	1 (11.1)	6 (66.7)	2 (22.2)
	Mild-moderate	4 (44.4)	3 (33.3)	5 (55.6)
	Moderate-severe	4 (44.4)	0 (0)	2 (22.2)
Control	Mild	0 (0)	3 (37.5)	3 (37.5)
	Mild-moderate	5 (62.5)	4 (50)	3 (37.5)

	Moderate-severe	3 (37.5)	1 (12.5)	2 (25)

Comparison of result Z= 1.3, p>0.05 (Mann-Whitney U test)

Effectiveness of treatments on percentage of consonants correct under different treatment showed that selected treatment drug provided more relief (p<0.01) compared to control therapy (p<0.01) after treatment. Both were statistically highly significant. The relief was maintained in case of control group; while it reduced to in case of trial group after follow up period. Comparison between both groups was not statistically significant (P>0.05) after treatment. Thus it was observed from statistical analysis that both the treatments have highly significant effect in the management of Articulations disorder and the treatment drug used in the trial group was significantly more effective than the treatment used in the control group.

Table 17:- Effectiveness of treatment on percentage of consonants correct under different treatment

Group	Stage	Mean	SD	N	Mean Difference	Paired 't'	p
Study	BT	70.0	12.4	9	13.0	3.89	<0.01
	AT	83.0	7.5	9			
	AFU	78.7	9.3	9			
Control	BT	68.0	9.2	8	7.9	4.37	<0.01
	AT	75.9	9.1	8			
	AFU	76.0	11.9	8			

Table 18:- Comparison of effectiveness of percentage of consonants (percentage change) based on treatment

Group	Mean	SD	N	t	p
Study	20.9	16.3	9	1.416	>0.05
Control	12.0	7.7	8		

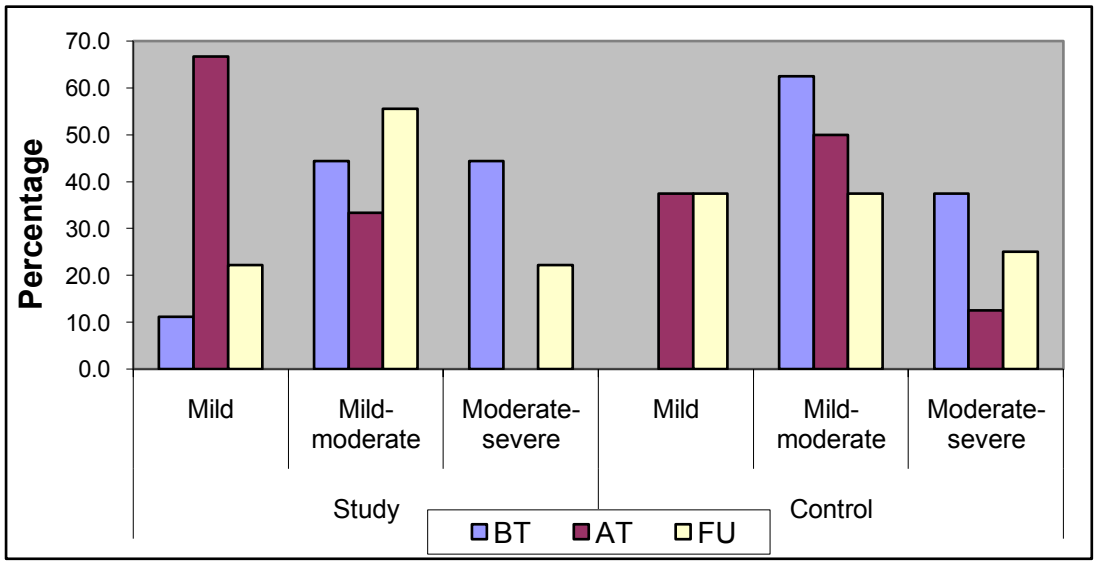


Figure 8:- Effectiveness of treatment on percentage of consonants correct under different treatment.

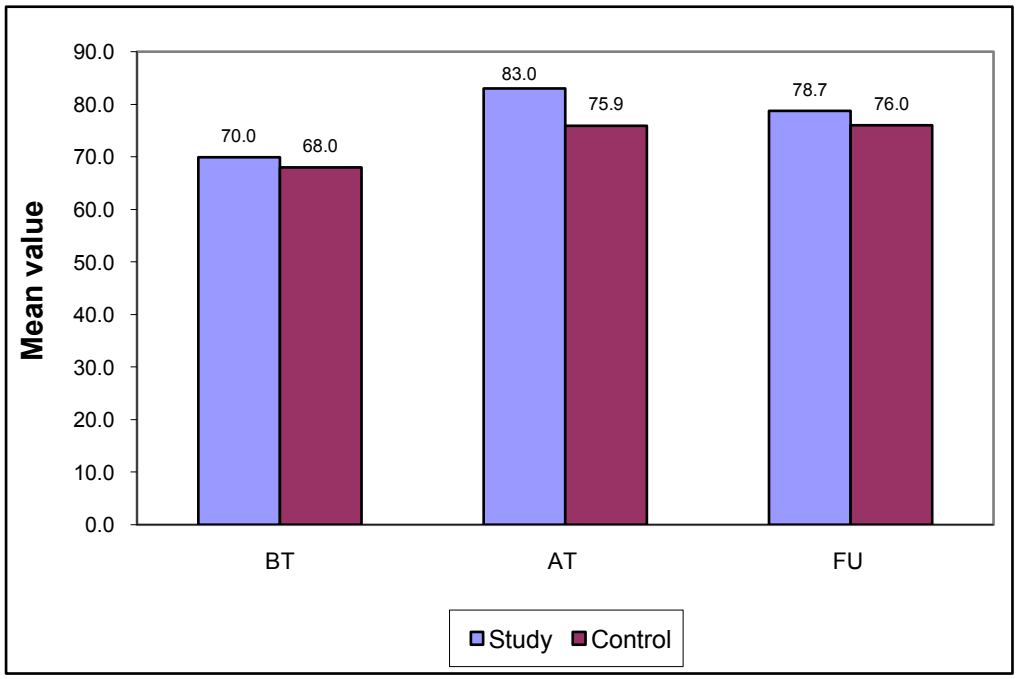


Figure 9: Effectiveness of treatment on percentage of consonants correct under different treatment.

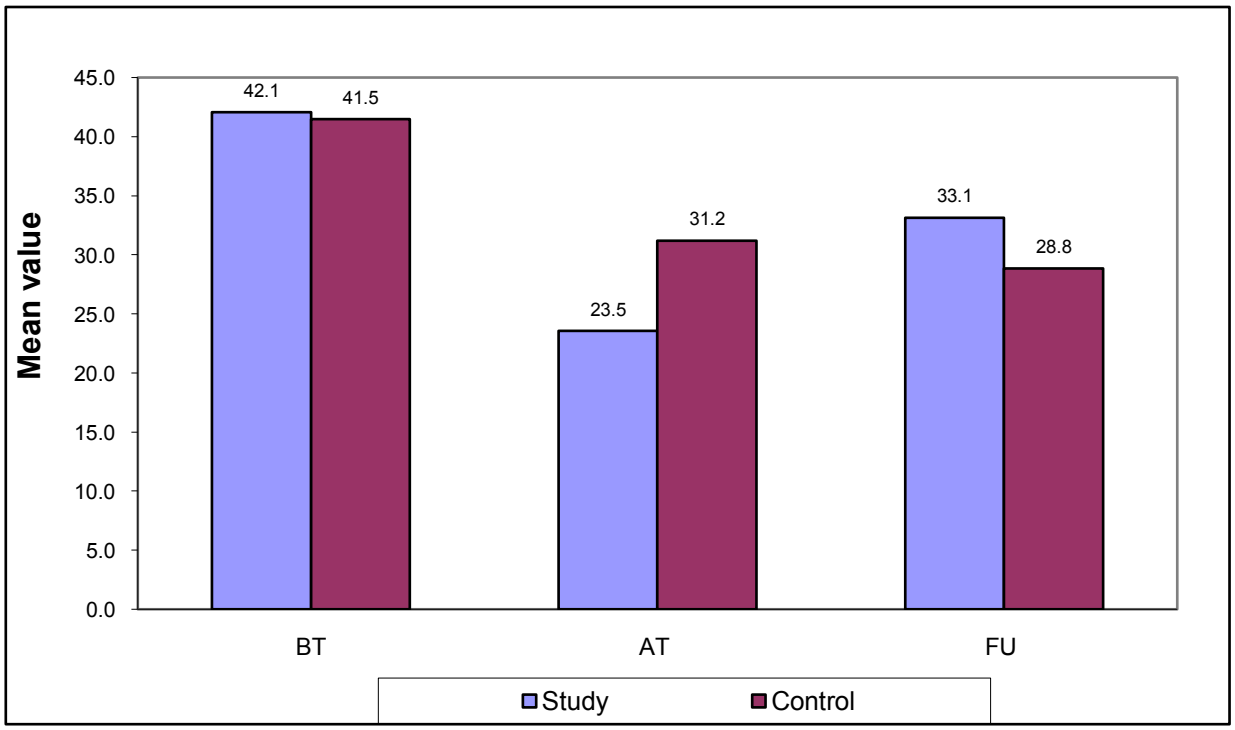
Table 19: ***Effectiveness of treatment on overall score (stuttering + Articulation)***

Group	Stage	Mean	SD	N	Mean Difference	Paired 't'	p
Study	BT	42.1	18.2	20	18.5	7.31	<0.001
	AT	23.5	11.2	20			
	AFU	33.1	15.3	20			
Control	BT	41.5	15.8	20	10.3	9.05	<0.001
	AT	31.2	15.0	20			
	AFU	28.8	16.2	20			

Effectiveness treatment on overall disorder (stuttering and Articulation):

Effectiveness of treatments on overall disorder (stuttering and Articulation) under different treatment showed that selected trial drug provided significant relief in both stuttering and articulation compared to control therapy after treatment. Both were statistically highly significant ($p<0.001$). Comparison between both groups was statistically significant ($p<0.05$) after treatment. Thus it was observed from statistical analysis that both the treatments have highly significant effect in the management of speech impairment and the treatment drug used in the trial group was significantly more effective than the treatment used in the control group. In total, the trial drug was effective in reducing the sign and symptoms of speech impairment. There was a significant reduction in sign and symptoms of speech impairment in the control group too. However, the result was not as effective as the trial drug. Thus it proved that trial drug was effective and had a sustained action in reducing the sign and symptoms of speech impairment.

Figure 10:- Effectiveness of treatment on overall score (stuttering + Articulation).



Probable mode of action of the *Vachadi Choorna*:

Vachadi Choorna contains nine drugs in equal quantity. The most important drug is *Vacha* because it has property to improve cognition, intelligence, ability to speak clearly and completely. The ingredients of *Vachadi Choorna* have predominantly *Laghu*, *Tiksana*, and *Snigdha guna*. These lead to *Anulomana* and *Srotoshodhana*. *Ruksha* & *tikshna guna* dispel the obstruction by *kapha* leads *indriya prasada* and increase the poise. *Snigdha guna* is similar to these lipids and thus it can be assumed that these drugs having *snigdha guna* nourish the brain. Analyses of the rasas reveal that maximum drugs have *Katu, Tiktha* and *Madhura* rasa in this combination. *Tikta rasa* being predominant in *Akasha mahabhuta* and *laghu guna*, increases the *sattva* part of mind. Appetizer (*Agnideepana*) function of *tikta rasa* increases the metabolism of body and neutralizes the complications of other drugs. Considering the pharmacological evaluation of *vipaka* of all the ingredients of study drug, *madhura vipaka* and *katu vipaka* are dominating. *Madhura vipaka* is said to increase all the body elements, including the brain tissue, nourish the mind and sense organs, alleviate the vitiated *pitta* and *vata* doshas, increase the vital strength and provide firmness to the body. Thus it can be assumed that it has nourishing effect on the brain. *Katu vipaka* on the other hand increases the overall metabolism in the body including the brain, helps in absorption of nutrients and neutralizes the complications of other drugs, thereby minimizing the nutrient deficiencies and stimulates all the sense organs to perceive their respective objects. Pharmacological evaluation of *Veerya* of drugs shows that *Usna Veerya* is dominating. *Ushna virya* by virtue of its *vata* alleviating property pacifies the vitiated *vata dosha* in the condition of speech impairment. At the same time *ushna virya* also increases the blood circulation in the brain. Majority of drugs have *Medhya Prabhava.* It has been mentioned by Nagarjuna in Rasa Vaisheshika Sutra that *medhya* drugs act mainly by their "*Achintya virya*" i.e. the *prabhava* i.e. unknown mode of action. This indicates that these drugs have direct impact on the *medha* (intellect). The exact mode of action of the *medhya* drugs is not very clear, but these drugs ultimately increase the overall cognitive capacity of the brain. Most of the drugs are having property to pacify *kapha vata*. Since speech impairment in *Ayruveda* is apparently similar to the condition *muka, minminatva* and *gadgadavaktvam* which are one of the *vata nanatmaja vyadhi*, the drugs by its *vata* pacifying property may help in alleviating the symptoms of speech impairment. *Kapha* pacifying property of the drugs helps in breaking the obstructions by *Kapha* and clearance of channels, which leads to clarity of sense organs (*indriya prasadana*) and proper functioning of the body as well as the brain. *Kapha* pacifying drugs have properties opposite to that of *tama dosha*, which help in dispelling the obstructions and normalizing the *tama dosha*, thereby keeping the equilibrium of *trigunas* and maintaining the proper functioning of mind. So trial drug combination is capable of reducing the vitiation by virtue

of their action against the vitiated *dosha* (body humours) and obstructed *Srotas* (channels of the body). Thus, it can be interpreted that effect of all the ingredients of the study drug was due to their above-mentioned properties.

To rule out possible side effects of the study drugs, clinical criteria were adopted. It included the documentation of information related to change in appetite, abdominal features, irritability, sleep etc. No adverse effects of the drug were observed during the study. This indicates the safety profile of the study drug.

Summary:-

The aim of the study was to evaluate the efficacy of *Vachadi Choorna* the in speech impairment in children up to 12 years. The study was conducted as a randomized control trial and the children in the control group were given speech therapy, of which efficacy has been proved by earlier studies by the scholars. Statistical analysis of the changes noted in the Stuttering Severity Instrument and Malayalam Articulation Test after treatment period in the children of the trial group showed improvement in speech. Both, trial and control groups showed highly significant ($p < 0.001$) results. The effect that was noted in the children of trial group was significantly greater than that of children in the control group ($p<0.05$) after treatment. Thus the efficacy in improving speech of the trial drug combination in the trial group and superiority of it over speech therapy – an intervention in the control group was proved.

Conclusion:-

The clinical study was aimed to evaluate the efficacy of *Vachadi Choorna* (an *Ayurvedic* powder formulation of medicinal plant parts) in speech impairment in children up to 12 years. The treatment provided to both groups were found highly significant ($P<0.001$) in reducing the signs and symptoms of speech impairment. Trial drug has found to have better efficacy in improving speech ($P<0.05$). No adverse effects of the trial drug were observed during and follow up period of the study. Limitations of the Trial were small sample size, unavailability of an appropriate control drug, Short term treatment and follow up period. So, recommendations are further research into more specific types of provision with longer duration of treatment & Follow up, Reconsideration of the therapy offered to children in terms of appropriateness, timing, nature, and intensity is required.

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