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RESEARCH ARTICLE

AYRES SENSORY INTEGRATION FOR THE CHILDREN WITH ATTENTION DEFICIT AND HYPERACTIVITY DISORDER (ADHD): A RANDOMIZED CONTROLLED TRIAL.

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Abstract

For intervention of children with a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD), there are many modalities. Sensory Processing issues are present in children with ADHD. There is a wide use of Ayres Sensory Integration (ASI®) to treat children with ADHD. But effectiveness of ASI® in children with ADHD is unknown. The purpose of study was to examine the effectiveness of ASI® Interventions on Participation of the child.

Method: Randomized controlled trial, double blind study. Eligible candidates were children having average intelligence with a diagnosis of ADHD, between age of 5 years and 12 years, sensory processing disorder (Some problems or definite dysfunction category on Sensory Processing Measure). Children included in the study received occupational therapy with either protocol.

Results: The children in ASI® Group, made gains that were significantly greater than the children in the other group on Goal Attainment Scale and ADHD Participation Profile. Large Effect sizes were found between and within both the outcome measures (1.87 & 0.939).

Conclusion: ADHD is complex disorder which embodies issues other than Sensory Processing and will be receptive to the other modes of intervention. ADHD does not only represent sensory processing issues. If existing, the sensory processing issues needs to be addressed specifically, as it will influence the global performance.

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Introduction:-

There are many modalities for treating children with a diagnosis of Attention deficit hyperactivity disorder (ADHD). Few of them are, Social Skill training(Gol D, 2005), Behavioral interventions, pharmacological intervention (Ghuman JK, 2008), sugar restriction, dietary supplements, mega-vitamins, or herbal treatments, EEG biofeedback, academic tutoring. Most of the time psychosocial interventions are recommended immediately after diagnosis and it is done before one starts pharmacological intervention. Commonly they are referred to receiving Occupational Therapy and frequently used therapeutic technique by Occupational Therapist is Ayres Sensory Integration® (ASI®) Therapy. But it is still considered as an unproven intervention.(Johnston, 2015). In this context, it is very important to study the effect of ASI® on the participation of the child in different life situations.

It is well studied that sensory processing problem in children with ADHD are more common than in typically developing children (Ghanizadeh, 2011). Also, it is known fact that sensory modulation disorder is present in children with ADHD. It is proven empirically by Dr. Miller using EEG technology and electro dermal response (Davies PL, 2010)(Abele-Webster L, 2012)(Shanley DM, 2001) (Dunne, 2002). Watemberg (2010) found motor coordination issues in this population. These coordination issues are also explained by Sensory Integration Theory(Watemberg N, 2007)(Ayres AJ, 1987)(OBrien JC, 2008).Yufeng (2010), while performing objective measurement of the balance dysfunction in ADHD children found that sensory inputs, the sensory integration, and/or the inhibition of excessive movement are impaired in ADHD children, which result in the balance dysfunction.

What is known?

Effectiveness of ASI® on sensory modulation disorder has been studied. Dr. Miller (2007) studied quantitatively the effectiveness of Occupational Therapy in children with sensory modulation disorder. Fedewa (2011) found that teachers preferred stability balls over the chairs for the children with ADHD for meeting up with children's sensory needs (Fedewa, 2011)and Denise Lynn (2004) found improvement in classroom behavior(Schilling., 2004), and legible word productivity(Schilling, 2003).Chu et al (2007) utilized occupational therapy with a sensory integration approach for the management of children with ADHD (aged between 5 and 11 years)(Chu S, 2007). Further research is required with larger numbers of participants in RCTs.

Ruth found out that adapting particular occupations of children with ADHD affect the routines and occupations of other family members. According to Ruth, this concept should be used by occupational therapists working with children who have special needs and their families (Segal, 1998).

What is not known?

But till now, effectiveness of ASI® in children with ADHD is not known. Also, researchers are taking into consideration the presence of sensory modulation disorders (SMD). They are not taking into account the presence of Sensory Processing Disorder (SPD). Other categories of SPD, Sensory Based Modulation Disorder (SBMD) also contributes to the attention and organization of the behavior issues found in the children with ADHD. Thus it is important to evaluate for sensory processing disorder (SPD) in general rather than considering only for sensory modulation disorder (SMD).

Rationale of the study:

From the literature review and clinical experience it is clear that Sensory Processing Disorder is present in children with ADHD. Also, there is a wide use of Ayres Sensory Integration to treat children with ADHD. But there is no study on effect of ASI® on participation of children with ADHD in life situations. Considering all these aspects, there is an urgent need to do study effects of ASI® on participation of children with diagnosis of ADHD. This will be a potentially useful contribution to patient care.

Aims and objectives:-

The purpose of study is to examine the effects of ASI® Interventions on Participation of the children with diagnosis of ADHD.

Method:-

All procedures performed were approved by Institutional Ethics Committee of Seth GS Medical College, KEM Hospital, Mumbai.

Trial design:

This randomized controlled trial (RCT) was a two group parallel trial. It was a double blind study. The Consolidated Standards of Reporting Trials (CONSORT) 2010 guidelines for evidence-based reporting of RCTs were used to report this trial. (Schulz KF, 2010)

Participants and their Recruitment

Eligible candidates were children having average intelligence with a diagnosis of ADHD and between age of 5 years and 12 years. The diagnosis of ADHD was according to the DSM-IV TR guidelines and on ADHD Rating Scale – Home Form score ≥ 80 percentile. These children had sensory processing disorder (Some problems or definite dysfunction category on Sensory Processing Measure). Exclusion criterion were other disorders in childhood like Conduct disorder, Cerebral Palsy, Childhood schizophrenia, PDD and IQ < 85 . Clinical diagnosis of Sensory Processing Disorder by the occupational therapist after comprehensive evaluation, including the Sensory Processing Measure, Clinical observations based on Sensory Integration Theory (Bundy, 2003).

Study settings

The study took place in department of Occupational Therapy of KEM Hospital, Seth GS Medical College, Mumbai.

Interventions

Children included in the study received occupational therapy with a frequency of 3 times per week for 6 weeks. During the study period the children received 18 sessions. In both the interventions procedure for evaluation, goal setting was same, to avoid confounding effect of the procedure.

Experimental group

Received interventions based on Ayres Sensory Integration®. These interventions were given in following ways.

1. Clinic based therapy (Direct intervention)
2. Parent and child education
3. Home Program

During direct intervention (face to face), the child and the therapist interacted in a large occupational therapy room equipped with sensory activities and toys (Sensory Integration Clinic). Suspension system was installed for giving vestibular input. Mainly enhanced sensory input (tactile, Proprioceptive and vestibular) given in a playful context which gave just-right challenge for the child. The child's imagination helped create a pretend situation where child interacts with sensory materials in an active, purposeful and fun manner. These things were guided by the parent's concern for the child. Fidelity guidelines for Sensory Integration Intervention described by Parham (2007) were followed. The chart of fidelity guidelines was stuck in the department as a reminder for the treating therapist. The key to this approach is asking questions moment-by-moment rather than using prescribed activities (Miller, 2006). This manualised intervention took into account principles of Ayres Sensory Integration® for clinical reasoning. The individual session of intervention was provided by Occupational Therapist or post graduate students of occupational therapy for about 45 minutes. Though thrice a week was recommended frequency of intervention, the children could manage to report 1-2 times a week for intervention. This was because of the busy schedule of the children related to academics. After the therapy session the child and parents were educated for Self-regulation of behavior based on the arousal level and sensory needs.

Control group intervention:

Activity Protocol was to control behavior and attention to the child. Activity Protocol included a variety of engaging Tabletop play activities (e.g., Arts and crafts, puzzles, blocks, reading stories, interactive games). It did not include sensory opportunities of tactile, vestibular and Proprioceptive system as done during Ayres sensory integration. Various behavior therapy techniques also incorporated into the session. The intervention was given by occupational therapist or post graduate students of occupational therapy. Each session lasted for 45 minutes. Few sessions of group therapy were also incorporated for social skill training.

Instruments Used

Screening instruments

The ADHD Rating Scale-IV (Home version)¹ is a reliable and easy-to-administer instrument both for diagnosing ADHD in children and adolescents and for assessing treatment response. Containing 18 items, the scale is in accordance with DSM-IV diagnostic criteria for ADHD. Parents graded the child's behavior on 4 point ordinal scale (0-3), which best describes the child's behavior. There are separate norms for boys and girls. The norms were for inattention, hyperactivity and total score.(Pappas, 2006)

Another screening measure was **level of Sensory Processing, Praxis and social participation** as evaluated by parent rated Questionnaire viz. Sensory Processing Measure (SPM). SPM is a parent reported questionnaire that analyses functional behavior related to sensory processing. Parents graded the behavior on 4-point Likert type scale (Ordinal scale). After completion of the form, the examiner produced eight standard scores in different domains, viz. Social Participation, Vision, Hearing, Touch, Taste & smell items, Body awareness, Balance & motion, Planning and ideas. The standard score for each scale enabled classification of the child's functioning into one of three interpretative ranges, viz. Typical, Some Problems and Definite Dysfunction.

Primary Outcome measure

The primary outcome measure of the study was questionnaire viz. ADHD Participation Profile, which measures the level of participation in life situations (Dependent Variable). For each item the gradation of difficulty for the child was No (0), mild (1), moderate (2), complete (3) and severe (4); (Ordinal scale). This level of difficulty was rated by parents/ caretakers.

Secondary Outcome measures

Also **functional improvement** was evaluated by Goal Attainment Scale. For setting up goals of the treatment, **Goal Attainment Scale (GAS)** was used. It is an individualized evaluative criterion referenced instrument. We used for measurement of changes in individual patients on individual goal. The expected outcome is stated in the middle level, with two levels each above and below it. The child and family was be involved in setting goals at each level, in order to ensure that they are realistic and relevant. GAS generates a 5- point ordinal scale. For each child 3 goals were set. SMART criterion was used. (SMART means Specific, Measurable, Achievable, Realistic and Time Bound).

Sample size

A total of 96 patients entered this two-treatment parallel-design study. The probability was 90 percent that the study will detect a treatment difference at a two-sided 0.05 significance level, if the true difference between treatments is 0.670 times the standard deviation.

Randomization: Sequence generation

We used a computer-generated list of random numbers for allocation of the participants. Participants were randomly assigned following block randomization procedures (computerized random numbers) to 1 of 2 treatment groups.

Randomization: allocation, concealment, mechanism

The allocation sequence was concealed from the researcher enrolling and assessing participants in sequentially numbered, opaque, sealed and stapled envelopes. Corresponding envelopes were opened by co-investigator only after the enrolled participants completed all baseline assessments and it was time to allocate the intervention.

Blinding

We kept patients and therapists giving the intervention blinded to the allocation.

Similarity of interventions

Both the groups received the intervention for 18 sessions. Each session was of 45 – 60 minutes duration. In both the groups the occupational therapist gave the intervention.

1

Results & Statistical methods:-

CONSORT 2010 Flow Diagram

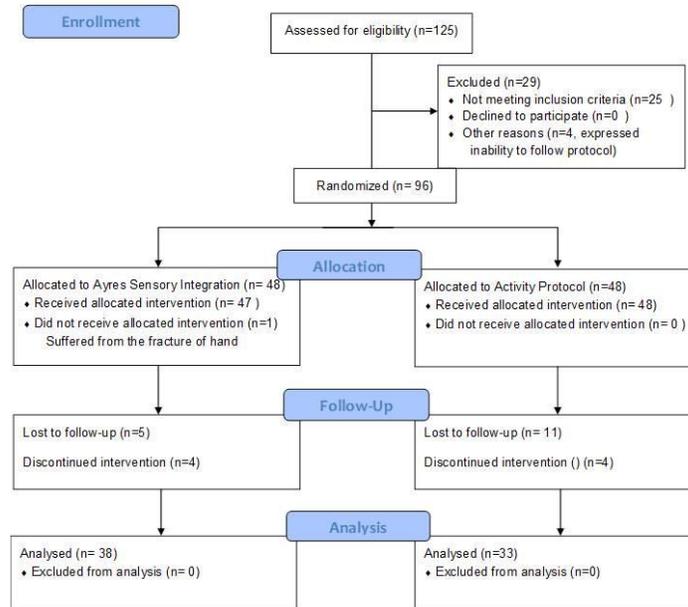


Figure 1:-consort 2010 flow diagram

The data were analyzed by using Statistical Package for Social Sciences Version 17 with descriptive analysis, Wilcoxon Signed Rank Test for within group difference, Mann Whitney U test for paired comparisons in significant cases with level of significance set at p value less than 0.05. Table 1 and 2 shows the age and gender distribution along with sensory processing issues of participants in the study.

Table 1:-Demographics

Group	Male	Female	Total	Age (in years)	
				Mean	SD
ASI®	31	7	38	7.625	1.91994
Activity Protocol	27	6	33	8.595745	2.252145

Table 2:-Sensory Processing issues as per Sensory Processing Measure

SPM DOMAINS	SOC	VIS	HEAR	TOUC H	BODY	BAL	PLA	TOT
MEAN	31.520 83	15.906 25	9.625	17.843 75	17.094 74	17.489 58	18.718 75	134.20 83
SD	5.9946 98	4.2154 56	2.0736 44	5.0603 27	4.9916 39	3.4212 8	6.3804 03	16.908 99
No. of children with Definite Dysfunction	68	7	0	8	10	6	19	77
% of children with DD	70.833 33	7.2916 67	0	8.3333 33	10.416 67	6.25	19.791 67	80.208 33
No. of children with Some Problems	92	44	17	52	52	53	55	96
% of children with DD	95.833 33	45.833 33	17.708 33	54.166 67	54.166 67	55.208 33	57.291 67	100

SOC: Social Participation, VIS: Vision, HEA: Hearing, TOU: Touch, BOD: Body awareness, BAL: Balance & motion, PLA: Planning and ideas.

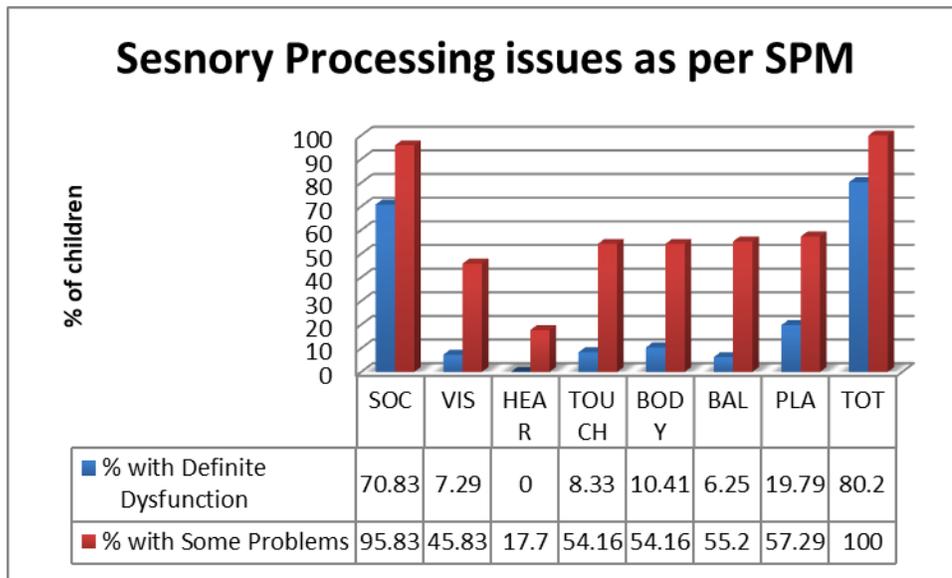


Figure 2: Sensory Processing Issues in study population

SOC: Social Participation, VIS: Vision, HEA: Hearing, TOU: Touch, BOD: Body awareness, BAL: Balance & motion, PLA: Planning and ideas.

All participants with baseline and 6-week data were included in analyses. The group means and standard deviations for changes from pretreatment to post treatment on standardized scales are noted.

As data do not meet the requirements of parametric tests (data on an ordinal), we used nonparametric statistical tests, such as the Mann–Whitney and the Wilcoxon tests. The significance of these tests is evaluated through the approximation of the distributions of the test statistics to the z distribution. The z value is used to calculate an effect size, such as the r proposed by Cohen (1988). Cohen’s guidelines for r are that a large effect is .5, a medium effect is .3, and a small effect is .1 (Coolican, 2009, p. 395).

Table 3:-Mann Whitney U Test for independent samples of ASI® & Activity Protocol

	U mean	U standard deviation	Z-score (absolute value)	Level of confidence for directional hypothesis
Before the intervention on Participation Profile	407	63.7	0.35	63.80 %
After the intervention on Participation Profile	407	63.6	3.58	99.98 %
After the intervention on Goal Attainment Scale	623.5	86.5	4.33	100.00 %

Table 4:-Comparison within the group by using Wilcoxon Signed Rank Test

Group	Pre		Post		Z- value	p-value
	Mean	SD	Mean	SD		
ASI®	13	10	4.3	5.3	-5.3028	0
Activity Protocol	12.29167	15.59591	8.574468	15.141	-3.4038	0.00068

Result is significant at $p \leq 0.05$

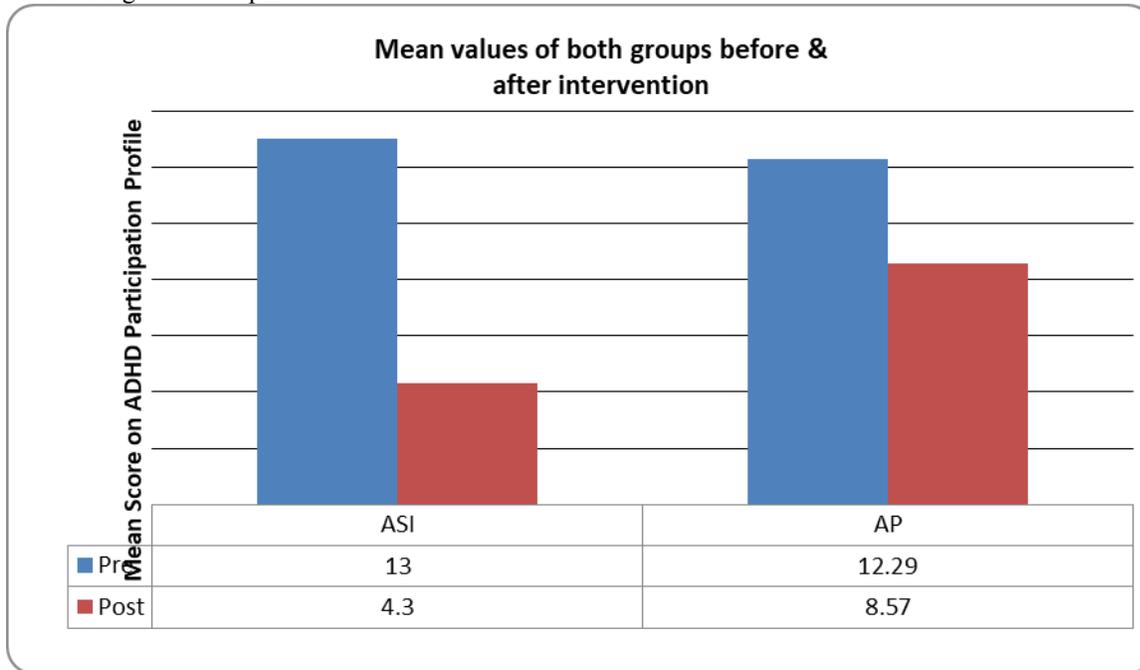


Figure 3:-Score on ADHD Participation Profile - Pre & Post intervention

Table 5:-Cohen d and its interpretation

Group	Cohen d value	Interpretation (Lenhard, 2016)
Between the groups on GAS	1.189963.	Large effect, Zone of desired effects
Within the group on PP ASI®	1.62	Large effect, Zone of desired effects
Activity Protocol	0.883	Large effect, Zone of desired effects
Between the groups on PP	0.939	Large effect, Zone of desired effects

The children in ASI® Group, made gains that were significantly greater than the children in the other group on GAS ($p < 0.005$ compared to Activity Protocol). Children in the ASI® group also increased significantly more than the other groups on Participation Profile ($p = .0$ compared to Activity Protocol)

Findings are displayed numerically in Table 5 and graphically in Figure 2. Large Effect sizes were found between and within the on both the outcome measures. (.939), and GAS (1.189).

Harms:

Parents who missed the one or more session reported in the next session about increased hyperactivity, not listening to them. Child was restless, had difficulty concentrating, showing attention seeking behavior and non-cooperative during homework.

Discussion:-

The findings of the study suggest that ASI® is effective in amending difficulties of the family and children with ADHD. Children in the ASI® group made significant changes compared to the Activity Protocol group on GAS and on ADHD Participation Profile.

Some studies (Vandana J Rathod, 2015) didn't follow key principles of Ayres Sensory Integration. Such studies should be appraised for the basis of key constituents of intervention. Thus it's difficult to verify that the therapeutic strategies used in the study represent the defined intervention but also makes the study unreplicable. This study successfully used a published, manualised approach to intervention of ASI®. The guidelines for intervention for the therapists were available on the website which included the Fidelity guidelines along with the activities. The document was available online all the time on the URL: issuu.com/hemantpn. The document consisted of all 10 items of The Ayres Sensory Integration Fidelity Measure along with the explanation (L. Diane Parham, 2011). Additionally, fidelity guidelines were constantly pasted on the wall of the unit as constant reminder for the treating therapist. We used the intervention only after screening children on the Sensory Processing Measure. Children with both sensory modulation and praxis were included in the study population. Thus it's logical equation that "Ayres Sensory Integration was used only on the clients with sensory processing issues".

Though outcome of both the groups was in the Zone of the desired effect, effect of ASI® was more than the activity protocol. This might be because of the sensory processing issues were addressed in the ASI® group. But one needs to be cognizant about the fact that ADHD does have only sensory processing issues. It's a complex disorder which embodies issues other than Sensory Processing and will be receptive to the other modes of intervention. But the sensory processing issues were not addressed as the infrastructure with suspended equipments, multi-sensory set up, playful approach were deficient in addition to methodology of intervention. ASI® group showed enhancements changes in Combination of Learning and applying knowledge & General Tasks and demands, Mobility, Self-care and Domestic life. Activity Protocol group showed progress in Interpersonal interactions and Relationships. Communication domain exhibited trivial gain in either of the group. Senior children (age more than 10 years) and girls responded better to intervention in both the groups. Age-related improvements in performance are extensively documented in the literature (M. Huizinga, 2006) (Hongwanishkul, 2005).

Though three times a week was recommended frequency of intervention in the protocol, but some of the children could not match this because of variety of reasons. Subjects who completed entire eighteen sessions were considered during analysis (Gupta, 2011). Considering this adherence to the total dosage of intervention the outcome in both the groups is warranted. With negotiated adherence, study demonstrated the play-based intervention was effective for improving the social play skills of children with ADHD aged 5 to 11 years in peer-to-peer interactions in the clinic and home environments (Wilkes-Gillan S, 2016). Other studies did not comment about the protocol adherence element (Shanley DM, 2001)(Vandana J Rathod, 2015).

Certainly the combination of therapies will give better improvement compare to individual therapy with only one approach as found by (Vandana J Rathod, 2015). Wide-ranging multidimensional intervention plan consisting of sensory integration and other non sensory psychosocial interventions decided after need of the individual goals might be better solution.

Goal Attainment Scaling and ADHD Participation Profile were complementary in their ability to measure individual change over time in children with ADHD. Using only ADHD Participation Profile could have caused many individual rehabilitation goals actually attained being missed in the outcome evaluation.

We used only hypothesis-driven outcome measurements. Participation was the target of the intervention. For that we used ADHD Participation Profile which is valid and reliable and responsive instrument (Nandgaonkar HP, 2017). ADHD Participation Profile is mainly designed as an outcome measure to report the progress. Many studies use the screening tools or diagnostic measure to evaluate as an outcome measure which may not be responsiveness to change. Responsiveness of ADHD Participation Profile was already is already examined (Nandgaonkar Hemant, 2018).

Conclusion:-

ADHD is complex disorder which embodies issues other than Sensory Processing and will be receptive to the other modes of intervention. ADHD does not only represents sensory processing issues. If existing, the sensory processing issues needs to be addressed specifically, as it will influence the global performance.

Ethical approval:

“All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.”

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