Research Protocol

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Dentistry Section

Oral Stimulation by 3-D Printed Speech-sensory Appliance Series to Evaluate Speech and Associated Oral Sensory Difficulties in Children with Autism Spectrum Disorder: Protocol for Randomised Controlled Trial

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ABSTRACT

Introduction: Oral sensory problems in Autism Spectrum Disorder (ASD) are mainly due to lack of sensory-motor synchronisation and incomplete neuromuscular development. Direct oral stimulation can play a significant role as a part of oral therapy, because the speech outcome by Speech Therapy (ST) has subjective variation and requires a long period of time. The other oral muscular therapy has lack of specificity and sensitivity. However, the direct oral stimulation in the form of appliance therapy has not yet been investigated.

Aim: To explore the precise role of Speech-sensory Appliance (SSA) on speech disorder and associated oral sensory problems in ASD children.

Materials and Methods: In this single-arm, randomised controlled trial, 40 ASD-diagnosed children between the age group of 4 to 11 years will be involved. The study participants will be split into two groups of 20 each at random. While the other group will be exposed to SSA+ST therapy, one of the groups will undergo SSA therapy. The speech therapist was unaware of the group of children who received both therapies (blind). Analyses of the results will be conducted utilising voice recordings and Visual Analogue Scales (VAS). Before and after therapy, the voice recording graph will be collected. Parents will be given a short questionnaire as part of the VAS to track any changes in feeding behaviour.

Keywords: Feeding behaviour, Oral muscular therapy, Oral therapy, Picky eaters, Speech therapy

INTRODUCTION

The Autism Spectrum Disorder (ASD) children show complete or partial lack of speech, delayed speech, speech inadequacy, deficiency in receptive, expressive speech and language impairment [1,2]. ASD children and adolescent usually show high prevalence for articulation and phonological errors, due to inadequate motor learning and imperfection in the structuring of word or phrase [3,4]. Motor speech disorder includes dysarthria and Childhood Apraxia of Speech (CAS) which has significantly low prevalence in ASD [5]. However, children and adolescents of ASD have higher rates of inappropriate prosody, which is distinguished by repetitions of words (echolia), high pitched words and phrases, and misplaced stress [5,6].

The accessory oral sensory problem mainly comprises of atypical feeding behaviour followed by grinding of the teeth, biting on hard object, and frequent drooling of saliva. ASD children usually show a limited selection of food, often referred to as “picky eaters” [7,8]. The limited selection in food leads to nutritional deficiency amongst the ASD children [9].

Speech Therapy (ST) is the central therapy followed by Augmentative and Alternative Communication (AAC), Oral Placement Therapy (OPT), Non Speech Oral Motor Treatment (NSOMT), and audio-digital techniques. ST is most useful for minimally verbal ASD children, high functioning autism and Asparagus syndrome [10]. However, ST is long standing process and speech outcome further depends upon the quality time spend by speech therapist [11]. Additionally, sensory profile of ASD participants and outcome of Occupational Therapy (OT) or Generalised Sensory Therapy (GST) has direct influence on speech outcome by ST [11]. AAC is based upon specific learning principle for speech communication outcome. Low-tech AAC included Picture-Exchange Communication System (PECS) and High-tech AAC consisted of electronic gadget such as Samsung galaxy tablet or iPad 2 (Apple) with voice output application [12-16], randomised trial and other clinical studies on AAC has been reported with significant improvement in spoken language communication and joint attention with minimally verbal ASD participant [12-16].

However, long term benefit of AAC in relation to sensory profile of ASD participants is questionable, due to short duration of the studies and no significant demonstration of sensory behaviour of ASD participants [12-16]. Therefore, the outcomes of these investigations must be determined in the future. OPT and NSOMT are non specific oral and para-oral muscular stimulation [17,18] Audio-visual techniques included music therapy [19], mobile application [20], computer game [21] and video-analysis [22]. However, all these techniques require careful evaluation, but music therapy [19] and “Mita” [20] mobile application observed beneficial outcome in ASD.

All the above-mentioned therapies are indirect stimulation and simulation for speech outcome. However, speech disorder in ASD is related to the oral-motor disorder, further simplified as a lack in synchronisation of oral sensory and motor receptors and their pathways [3-5], and also the impairment in motor programming and planning [5]. Hence, direct oral stimulation in the form of oral

sensory-motor stimulation may be the significant need for ASD [5]. Oral sensory stimulation may have precise role to balance the sensory needs and overload, which may be beneficial for articulation errors, phonological errors, stress while speech production, misplaced stress, high pitched-sound and phrases [23]. Furthermore, sensory-guided plate appliance therapy has been already observed in patient with cleft lip and palate [24] and Downs Syndrome [25]. Hence, the present study has developed 3D printed SSA to stimulate oral sensory-motor areas for better speech outcome and to control the atypical feeding behaviour.

Hence, the present study aimed to explore the effect of novel 3D printed SSA as a direct oral stimulation in comparison with ST in ASD children. The study will provide the role of SSA therapy as a single therapy or in combination (SSA+ST) for better speech outcome and feeding behaviour.

REVIEW OF LITERATURE

The Autism Spectrum Disorder (ASD) cannot be completely cured because it is ingrained in the body throughout life. Thus, the only way to deal with the sensory issues in ASD is through therapy. For generalised sensory issues, OT and sensory integration treatment are frequently employed, and the results of these therapies will be significant if they are initiated earlier in life. Oral sensory issues are not specifically addressed by oral sensory therapy. As a form of indirect stimulation, ST and modern AAC have been applied to speech communication. However, due to the nature of oral sensory abnormalities in ASD and the fact that oral tissues are one of the most densely innervated portions of the body in terms of peripheral receptors, direct oral stimulation may significantly affect speech development and associated oral sensory problems. Oral tissues have a significant number of receptors which are profoundly and broadly distributed [26]. The main somatosensory cortex contains the final representation of oral sensation [26].

To address speech problems and other sensory issues in ASD, the current study has designed a 3D printed SSA. The fricative contact between the palate circumference and tongue will produce the most speech sound possible [27] and stimulation to this area may have a stronger effect on speech. To stimulate the oral sensory region, SSA utilises a wide range of vibration patterns created by a significant number of vibrators. There is no noise or turbulence inside the mouth as a result of the smooth operation and precise stimulation provided by intraoral vibrations. In addition, it might be able to regulate air volume from the laryngeal component through the final termination of the vocal sound, giving it superior control over phonological error, nasal sound, and high-pitched sound.

Additionally, it may have a soothing impact intraorally as a result of balancing the sensory requirements in all sections of the oral cavity, not only the palatal region. The Bite Sensory Device (BSD) was created especially for feeding and eating behaviour. The periodontal ligament that surrounds the teeth as well as other dental tissue may be stimulated by BSD. Children with ASD who have a low oral sensory profile (hyposensitive) may experience more sensory patterns from BSD, which primarily involve putting objects in the mouth for better stimulation. BSD may balance the necessary sensory need if it has a medium to hard silicon rubber consistency, a “U”-shaped frame, and medium to strong vibration for 20 minutes every hour. The same is true for ASD participants with a strong oral sensory profile, where BSD can be quite effective in reducing sensory requirement (hypersensitive). Oral hypersensitivity may be diminished by applying more pressure to a “U”-shaped frame made of soft to medium silicon rubber and slowly vibrating it for 20 minutes per hour.

In addition to local stimulation, SSA may be efficient in central stimulation. The findings of previous Magnetic Resonance Imaging (MRI) studies of oral stimulation and its representations in higher centers have shown that stimulation of the inferior frontal gyrus (IFG, Broca area) and higher activation of the amygdala, using the occlusal interfence of gold crown, are related to social language processing and social attention [28-34]. ASD manifests more severe abnormalities in the amygdala, notably a reduction in the volume of the right amygdala [33,34].

To sum up, ST plays a big role in improving communication and speech [35]. In functional speech disorders without sensory integration, ST is very beneficial. However, ST for sensory integration problem in speech required the most time [36]. Additionally, sensory issues and the amount of time a speech therapist spends with a child affect the success of the speaking process [35]. As a result, adding another therapy is necessary to boost the effectiveness of ST. AAC can be helpful to some extent, but it needs to be evaluated because it is another form of indirect stimulation. Non Specific Oral Muscular Therapy or NSOMT and OPT, focuses mostly on jaw and muscle strengthening without any sensory stimulation, much like OT. As a result, stimulating the oral sensory region in ASD may be important to enhance speech outcomes and associated oral sensory difficulties. In patients with functional articulation disorders such as cleft lip and palate and Down syndrome, oral stimulation has a significant role in improving speech and feeding patterns [24,25]. It has already been established that speech pathologists and speech appliances work together to treat patients with cleft lip and palate [35,37-38]. The 3D printed SSA series for oral stimulation have therefore been created in the current work and the study will explore its function further, both on its own and in conjunction with ST.

MATERIALS AND METHODS

Study is planned as a single arm, randomised controlled trial and will be carried out in special schools and rehabilitation centres at Nashik, Maharashtra, India under the observation of Datta Meghe Monitoring Committee (DMC). All the study details will be informed to parents, school teachers of special school, and in-charge of therapy centre. Written consent will be obtained from them before starting the study. The data obtained during the course of the study will be treated under the applicable Data Protection Law (EU General Data Protection Regulation- GDPR-2016/679) [39]. The complete duration of the study will be 18 months [39]. The reference number of randomised controlled trial (REF/2020/09/036975, www.ctri.nic.in).

Study was presented in front of Institutional Ethical Committee (IEC) and after the approval (DMIMS(DU)/IEC/2018-19/7593) from IEC, study was further registered for Central Trial Registry india (CTRI/2020/12/029597,04/12/2020) for RCTs.

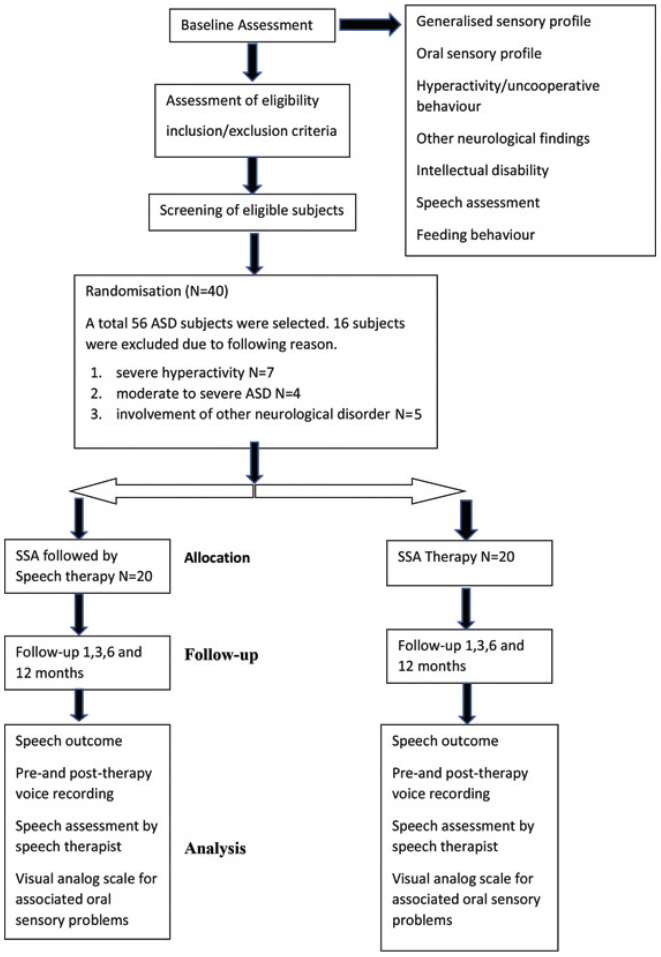
Inclusion criteria: Minimally verbal ASD children between the age group of 4-11 years, who meet the criteria of Diagnostic and Statistical Manual of Mental Disorder (DSM-V) [40] and International Classification of Diseases (ICD-10) [41] will be included in the study. ASD diagnosis was confirmed by the Psychologist, Psychotherapist or Paediatric Psychologist.

Exclusion criteria: Children with severe autism, ASD children having other medical complication or associated with multiple drug therapy, those ASD children associated with any syndrome, those diagnosed with other form of neurological disorder, will be excluded from the study. Also ASD children who suffered from severe hyperactivity and were unable to sit at one place and the children whose parents did not give their consent will also be excluded from the study.

Sample size calculation: Sample size will be calculated using the formula $n=\{(Z_{\alpha/2}+Z_{\beta})^2*2*\sigma^2\}/(d)^2$.

$Z_{\alpha/2}$=the critical value of the normal distribution at $\alpha/2$ (for a confidence level of 95%)=1.96, Z_{β}=the critical value of the normal distribution at β (for a power of 80%)=0.84, σ^2= the variance=263.41 (obtained from previous study) [12], and d=the likely difference between two sample means=84.29-73.67=10.62 (obtained from previous study) [12].

A total of 40 ASD participants between the age group of 4-11 years will be randomly selected using computer generated list from the therapy centre and special school, under the observation of DMC. The comfort of the intraoral device was examined in a pilot study on 10 ASD patients. The two groups in the pilot study each got ST alone in group 1 while SSD therapy was administered first in group 2. Nevertheless, group 1 was changed to receive SSD therapy alone in order to assess the clinical validity of the therapy as per the discussion with speech therapist. As a result, participants with ASD who meet the eligibility requirements will be randomly assigned using block randomisation for SSA (Group I: N=20) and Combination (SSA+ST) therapy (Group II: N=20) therapy (https://randomiser.at/). Allocation concealment will be performed by the in-charge of special school and therapy centre using clear opaqued sealed envelope as per their enrolment and assignment. The consort flowchart has been described in [Table/Fig-1].

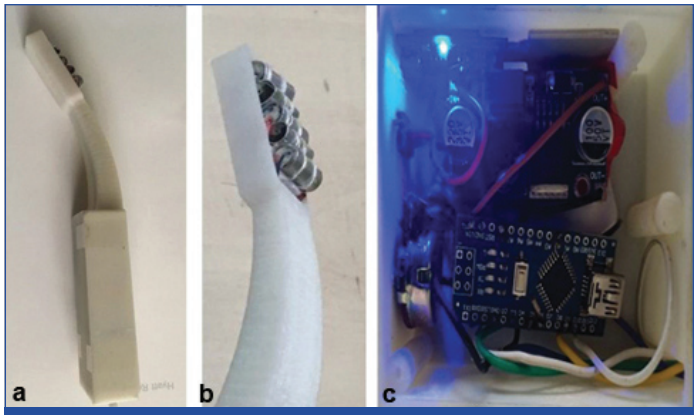


[Table/Fig-1]: CONSORT flowchart.

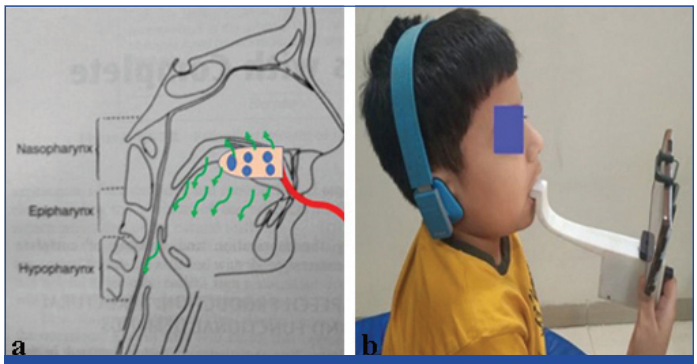
The three-Dimensional (3D) printed SSA series will be grouped in two types. Type 1: SSA and Type 2: Bite Sensory Appliance (BSA).

Speech-Sensory Appliance (SSA), [Table/Fig-2,3]: The device was registered under provisional patent (TEMP/E-1/32979/2020-MUM). This device has main indication for speech errors and it has two parts as described below:

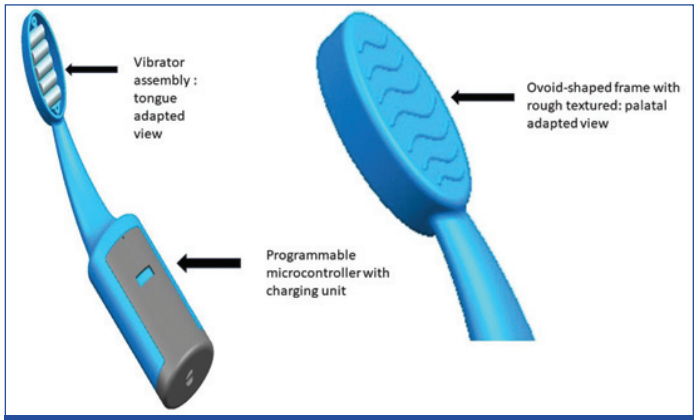
Head region [Table/Fig-2-4]: It has a driving, vibrator component that was 3-D printed out of Acrylonitrite Butadiene Styrene (ABS). It has five vibrators installed in alternate positions, and the layout can be changed to a cross parallel arrangement. It is made up of a number of vibrators that can be combined to produce different vibration patterns that can stimulate the oral sensory region. The device prototype had a rectangular shape. The final design was altered, though, to account for the hard and soft palate circumference. The final design has a rough texture for better sensory stimulation and a roughly oval form to accommodate the palate's size.



[Table/Fig-2]: Speech-Sensory Appliance (SSA) prototype design, head and programmable microcontroller. a. Prototype design b. Head with plurality of vibrators c. programme microcontroller.



[Table/Fig-3]: SSA Prototype Design 1 application with directional stimulation intraorally. a. Diagramatic Representation b. Patient protocol.



[Table/Fig-4]: SSA final three-Dimensional (3D)-printed design with palatal and lingual view.

Handle region: It contained a micro-controller that could be programmed. Each vibrator is attached to a microcontroller's pulse width modulation pin, which enables the vibrator to turn on and off and adjust its frequency to the desired range. By offering a knob that generates alternate mode and serial overlapping mode of vibration frequencies, the device adjusts the vibration frequency. Additionally, altering the vibration interval may result in varied vibration patterns that, depending on the needs of ASD subjects, activate various oral sensory regions.

Bite Sensory Appliance (BSA) [Table/Fig-5]: BSA is mostly utilised to balance sensory overload and the oral sensory requirement. Therefore, it might help with auxiliary oral sensory issues such unusual eating, teeth grinding, or biting on hard objects. The appliance has a flexible "U"-shaped intraoral frame with three layers that match the upper/lower teeth occlusal surfaces. Additionally, it externally links to programmable microcontroller. The outer and inner tooth surfaces were enclosed by the two lateral levels of the letter "U." The occlusal surfaces of the upper and lower teeth are in the middle. By establishing a 3D designing space for it, the vibrator device was positioned inside the center layer. A single vibrator

was inserted at the anterior site, and two vibrators were implanted bilaterally at the posterior region. At the vibrator site, the middle layer was appropriately reinforced. Depending on the sensory need, the intermediate layers texture ranged from medium-hard to medium-soft. The intermediate layer texture was adjusted from medium to hard with a high vibrational frequency, if the ASD child had oral hypersensitivity (sensory overload) as evidenced by biting on hard objects, grinding of the teeth, and a preference for hard food. The middle texture was changed from medium to soft silicon layer with low vibrational frequency if the child displayed signs of oral hyposensitivity (sensory seeking), such as placing an object in the mouth and keeping it there for an extended period of time, drooling, and a preference for soft food [42].

[Table/Fig-5]: Bite sensory appliance 3D-printed design.

Interview with in-charge of special school and rehabilitation center (First 1 month): Prior to the start of the study, the interview will be scheduled with a special school and rehabilitation facility administrator. They will be given an explanation of the study procedure and the safety features of the appliances. With the assistance of occupational and speech therapists, the current condition of ASD participants will be evaluated. The parents will be asked for a thorough case history. The parents' written consent will be acquired.

Baseline measures: Participants with ASD will be prompted to use three-letter words like cat, dog, and boy while being observed by an occupational and speech therapist. Its duration is for 2 months. A person will be urged to say a brief sentence or phrase, if they can do so without feeling too stressed. Participants with speech issues or hyposensitive features will, nevertheless, be provided enough time for occupational treatment or other forms of sensory therapy. The individuals with ASD will be divided into three groups based on the results of the speech evaluation. Group I will have children who are above average, group II will have children who are average, and group III will have children who are below normal. Speech errors in group I are exceedingly minimal, and the children in the above-average group and those who are Typically Developing (TD) will be very similar. The speech characteristics used by the average group (Group II) were completely in-appropriate, including speech rate, word count, speech sound, and loudness. For an average group, speech sound will be quite difficult. Many children with ASD will speak with echolalia, nasal noises, loud speech, and stress. The Group III will speak more slowly, use fewer words, and make nasal sounds with obvious echolalia. They also speak louder than the other groups. To assess oral sensitivity in connection to feeding behaviour, the parents will receive questionnaires. A limited problem with food selection, feeding behaviour, and mastication will be indicated by the Visual Analog Scale (VAS) of 0-2. A score of 2 to 5 indicates a slight problem, a score of 5-8 a moderate problem, and a score of 8 to 10 a severe problem in food selection, atypical eating behaviour resembling "picky eaters" and a considerable problem with mastication.

Pre-therapy voice recording: The time duration is for 3 months. Voice recording sessions during therapy will be conducted using a digital portable voice recorder with high sensitivity recording and background noise cancellation. With the use of an AAC (low-tech) picture, exchange communication system or a digital tablet system, the children will be encouraged to say three-letter words like "cat," "dog," and so on (HIGH TECH AAC). For better communication and teamwork, voice recording will be done initially with the elder participants so that they may serve as role models for the younger participants. If any of the participants exhibits un-cooperative behaviour, the study will suspend until the subject exhibits proper behaviour, at which point it will resume. For improved child cooperation, study sessions would be scheduled early in the morning. Both on the device and on the computer, the voice recording will be saved in the appropriate file and folder.

Post-therapy voice recordings: The time duration is 6 months to 12 months. The SSA appliance will be operated for 5 to 10 minutes at first. Once the children starts showing interest in the process, the duration will be incrementally extended. Additionally, the SSA has a smartphone socket near the handle area, which will aid in engaging the ASD subject and ensuring the efficient operation of the SSA. Depending on how much interest is generated by the participants, the length of the SSA will be raised from 10 to 20 minutes. SSA therapy will be followed by usage of a Bite-Sensory Appliance (BSA). Again, the length of BSA will depend on how interested participants are in learning about ASD. Initial sessions will last 10 minutes for SSA therapy and 10 minutes for BSA. Depending on the level of interest shown by individuals with ASD, the time will be extended to 20 minutes per session. Appliance therapy will be administered to younger participants with assistance from parents or school staff. For the subject with a small mouth opening, an appliance will be made specifically for their size and shape. Similar to pre-therapy, post-therapy voice recording will be carried out six and twelve months afterwards.

Primary outcome: The main result will be the evaluation of speech. The speech therapist who is not a participant in the trial will evaluate the speech outcomes without knowing whether group will get SSA therapy or combination (SSA+ST) therapy. From a distance of around 75 cm, the speech therapist will evaluate the patient's speech while making sure to maintain correct eye contact. The individual with ASD will receive roughly 45 minutes of ST.

Speech Assessment A: There will be two stages to the speech analysis: The first step will be represented by a participant's spontaneous speech, the number of words they use, and word repeats. Step II will identify the speech sound analysis, which will include pronounciation fluency, loudness, stress when speaking, and sound resonance.

Score: There will be a score of 0 to 5 for the speech analysis. The subject will receive a grade of 0 if they were able to speak normally and spontaneously with an average amount of words while avoiding nasal sounds, speaking loudly, and using speech stress. The speech sound in first grade will be on the edge, with potential connections to loudness, nasality, and resonance. Both speech mechanics and speech-sound issues will be mildly problematic for grade 2. It could be caused by slurred speech, few words being said, slight echolalia, and slight speech stress, similar loudness, resonance, and nasal sound but with a minor increase. When it comes to speech mechanics and sound, grades 3 and 4 will be considered moderate and severe, respectively. During the course of the study, the reliability of the scoring criteria will also be assessed

Speech Assessment B: Voice recording graphs will be used to compare pre-and post-therapy voice recordings. The major result will be to determine whether speech has improved noticeably following therapy. To ascertain the variations in speech sound

quality, The MATLAB® Release 2022a (R2022a) software that is included will be used.

Secondary outcome: Associated oral sensory difficulties were also observed and studied. The most frequent oral sensory issues are atypical feeding patterns, which are followed by teeth grinding, saliva dribbling, and putting everything in the mouth. Following the speech evaluation, the VAS scores before and after therapy will be compared and a thorough parent interview will be conducted. On the basis of the VAS score and the parents' interview, grades 0-4 will be applied.

Grade 0: No problems with eating, chewing, teeth grinding, or drooling.

Grade 1: Mild issues with food selection, chewing, teeth grinding, and saliva dribbling were present.

Grade 2: Featured oral hyposensitive traits like a preference for soft food, holding bolus intraorally for prolonged period of time, and putting anything in the mouth.

Grade 3: Noted signs of oral hypersensitivity, including a liking for hard foods, biting on hard objects, and frequent saliva dribbling.

Grade 4: It is characterised by atypical eating habits, commonly referred to as "picky eaters" with a small range of acceptable foods, which also depends on oral sensitivity; may have displayed mixed sensitivity (Fluctuations from oral hypersensitivity to hyposensitivity or vice-versa).

During the course of the study, the reliability of the scoring criteria will also be assessed.

The protocol for assessment has been summarised in [Table/Fig-6].

Time point	Pre-Therapy	Therapy	Post-therapy			
			1 month	3 month	6 month	12 month
Enrolment:	X					
Eligibility screen	X					
Informed consent	X					
Screening	X					
Baseline data collection	X					
Randomise subject allocation	X					
Interventions:						
SSA		X				
SSA+ST		X				
Assessments:			**XS1 XS1 XS1 XS1**			
Primary outcome			**Y XS2 XS1 XS1**			
Secondary outcomes			**Y Y Y**			

[Table/Fig-6]: SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials).
X: Primary outcome: XS1: Pre-therapy and post-therapy voice recording graph comparison
XS2: Speech assessment by speech therapist who is not part of the examination
Y: Secondary outcome: Using a Visual Analogue Scale (VAS) parents are questioned before and after therapy to determine the child's feeding behaviour status

Problems Anticipated

- Generalised sensory problems and hyperactivity might be the biggest challenge.
- Attention span of the children.
- Overall cost of the equipment.

Participants with ASD who experienced moderate sensory issues and hyperactivity will be given enough time to complete the study. Furthermore, an occupational therapist who was familiar with the children will supervise the therapy sessions.

Benefits and risk to participation: SSA is a non invasive gadget based on vibrational stimulation that cannot negatively impact teeth and oral health.

STATISTICAL ANALYSIS

All the results will be tabulated and statistically assessed by means of Statistical Package for Social Sciences (SPSS) software (version 20© SPSS, Chicago, IL). Mean values with standard deviation will be calculated. Values will be considered significant when p-value <0.05. The normality of data will be analysed using the Shapiro-Wilk test. Normally distributed data (mean±SD) will be compared using Student t-test. Data with non normality (median) will be treated using Mann-Whitney U test and Wilcoxon signed rank test.

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