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ANKARA SOCIAL SCIENCES UNIVERSITY INSTITUTIONAL ETHICS COMMITTEE OF SOCIAL SCIENCES AND HUMANITIES RESEARCH AND PUBLICATION



CERTIFICATE OF ETHICS APPROVAL

RESEARCH METHOD	Randomized Controlled Trial
STUDY TITLE	Effect of Ayres Sensory Integration Therapy on Sensory, Motor, Cognitive, Behavioral Skills And Social Participation in Children With Attention Deficit Hyperactivity Disorder:
	Randomized Controlled Trial
PRINCIPAL RESEARCHER NAME SURNAME	Busra KAPLAN, OTR/L
COMMITTEE DESICION	APPROVED
	ASSISTANT RESEARCHERS 1- Prof. Dr. Gonca BUMIN 2- Ass. Prof. Hakan OGUTLU 3- Prof. Dr. Mehmet Hakan TURKCAPAR



ANKARA SOCIAL SCIENCES UNIVERSITY ETHICS COMMITTEE APPROVAL CERTIFICATE APPLICATION FORM



STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

1. Study Title:

EFFECT OF AYRES SENSORY INTEGRATION THERAPY ON SENSORY, MOTOR, COGNITIVE, BEHAVIORAL SKILLS AND SOCIAL PARTICIPATION IN CHILDREN WITH ATTENTION DEFICIT HYPERACTIVITY DISORDER: RANDOMIZED CONTROLLED TRIAL

2. Purpose and Importance of Research:

According to the definition of the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), Attention Deficit Hyperactivity Disorder (ADHD) is a behavioral and neurodevelopmental disorder characterized by inattention, impulsivity and hyperactivity, negatively affecting the functionality and development of the individual. It has been reported to be among the most common disorders with a prevalence of over 5% in childhood (1, 2).

In the diagnosis of attention deficit and hyperactivity disorder, the presence of inattention, hyperactivity and impulsivity problems are the main symptoms. inattention in children with ADHD; It is manifested by behaviors such as short attention span, avoidance of tasks, inability to focus, daydreaming, and disorganization. Hyperactivity refers to excessive motor activity, excessive fidgeting and speech impulsiveness that are not appropriate for the situation. Impulsivity, on the other hand, manifests itself with features such as haste, not being able to postpone requests, having difficulty interrupting others' words and waiting for their turn, and making important and sudden decisions without considering long-term consequences (2, 3).

ADHD findings affect the behavioral, emotional, academic, social and cognitive functions of children, and behavioral outcomes that are not compatible with the age of the children can be observed. These symptoms significantly affect children's activities of daily living, academic skills and social participation. In addition, because it continues throughout life, it negatively affects the quality of life of family members such as parents, siblings, and caregivers (4).

Given the multidimensional nature of ADHD, current research has largely focused on cognitive and behavioral skills related to attention and executive functions, or social behavioral skills such as social participation and impulsivity, but insufficient attention has been paid to sensorimotor skills. However, the literature indicates the presence of sensory integration problems in children with ADHD. Sensory integration is defined as the neurological process in which the person processes the sensory experiences from the body and the external environment in a way that allows the body to be used meaningfully and purposefully (5). This process consists of different steps in which the central nervous system recognizes, organizes, perceives, interprets and responds to sensory information (6). Sensory integration disorder (DDD) is the general descriptive expression used for the processing problem in one or more of these steps. Researchers divide DDD into two basic classes as sensory modulation and sensory perception-based disorders (7).

Sensory modulation disorder has two basic manifestations: above-normal reactivity (defensive and avoidant responses) and below-normal reactivity (poor recording). Difficulties in attention, emotion regulation, and activity, avoidance of sensory experiences, sensory seeking, and poor self-esteem are behavioral traits that can be seen in individuals with sensory modulation difficulties. Sensory perception-based disorders are; poor postural-ocular control, sensory discrimination, body awareness, difficulties with vestibular-based bilateral integration and sequencing, and somatodyspraxia. Behavioral consequences of sensory integration disorders based on sensory perception can be seen as poor self-esteem or self-efficacy, avoidance of motor activities, weak fine and gross motor skills, visual-motor coordination and organizational skills, and sensory seeking (7). Sensory modulation problems are determined by family interviews and caregiver scales (Sensory Profile or Sensory Processing Scale), while sensory perception-based difficulties are determined by standard tests (Sensory Integration and Praxis Test) and in some cases, caregiver scales (8).

In the 1950s, Jean Ayres developed the theory of sensory integration and defined typical sensory development, defined sensory integration disorder in which we defined atypical sensory-behavioral responses, assessment tools and the way of applying Ayres Sensory Integration therapy (5, 9). In studies on Ayres Sensory Integration therapy, it is stated that when the intervention results are examined, improvement is observed in the areas of sensory, motor, cognitive, behavioral, social participation, and opactional performance (10).

Many studies conducted with individuals with ADHD report that their ability to perceive and process sensory information is affected (11-14). In addition, it has been shown that children with ADHD have difficulties in producing appropriate sensory responses at school, at home and in social environments in relation to their sensory processing difficulties (11), and these difficulties cause problems in daily living activities and performance in children (15, 16).

In studies conducted with children with ADHD, the presence of problems related to sensory processing was determined by both behavioral and neurophysiological measurements. Electroderm In a study conducted with skin responses, it was found that children with ADHD had more sensory reactivity responses than the control group (12). Another study conducted with EEG showed that children with ADHD with tactile sensitivity and children with ADHD without ADHD differ in the processing of somatosensory brain areas (13). Studies evaluating behaviors have revealed results that support these neurophysiological findings. Dunn and Benett's study using the Sensory Profile (DP) family scale revealed that individuals with ADHD differ in all 14 subtest sections of the DP family scale, including hearing, touch, multi-sensory processing, emotional/social responses, and behavioral outcomes (11). In another study conducted with the same scale, individuals with ADHD showed higher sensory reactivity responses than their controls, supporting previous findings (14). Although there are many studies using family scales such as DP, which measures sensory modulation skills in individuals with ADHD, there are limited studies evaluating sensory perception and sensory perception-based problems. In another study, individuals with ADHD had lower scores in the somatosensory perception tests of the DBPT when compared to the healthy group, and it was revealed that these individuals had a weak tactile and proprioceptive perception (13).

Although there are studies in the literature showing the presence of DDD in children with ADHD, most researchers have studied a similar profile, such as sensory modulation disorder, and few have investigated all components of sensory integration (such as sensory perception, praxis) (17). More research is needed to confirm the effects of Ayres Sensory Integration therapy in children with ADHD and the possible relationship between DDD-based difficulties in activities of daily living and ADHD symptoms. In our study, it was aimed to investigate the effect of Ayres Sensory Integration therapy on sensory, motor, cognitive, behavioral and social participation in children with ADHD in the light of extensive literature and recommendations.

3. Benefits and Risks Expected from Study

The evaluations to be made within the scope of the study do not involve any risk. At every moment of Ayres Sensory Integration Therapy applications, there will be at least one researcher, including our volunteer child and their parents. Considering all this information, participation in our study does not pose a risk. Difficulty with sensory and motor skills is a common problem for children with attention deficit hyperactivity disorder. With a structured sensory integration therapy application, it is aimed to reduce the sensory, motor and cognitive difficulties of children in their daily lives.

4. Materials and Methods

4.1. Study Place:

In this research, PhD student Büşra Kaplan, Dr. Hakan ÖĞÜTLÜ, Prof. Dr. Hakan TÜRKÇAPAR and Prof. Dr. Gonca BUMİN will take part in the evaluation, data analysis and writing stages. The research will take place in the pediatric rehabilitation unit of Hacettepe University, Department of Occupational Therapy.

4.2. Time to Study:

The study is planned to be completed between February 2023 and April 2024, starting immediately after the approval of the ethics committee.

4.3. Study Population, Sample, Research Group:

Study group and control group will be compared in the research. The change between the last evaluation and the first evaluation will be calculated and a comparison of this change between the two groups will be made. T-test will be used in independent groups for this comparison. The effect size was predicted to be 0.8. With 5% margin of error and 80% power, the sample size was calculated as (45 + 45) 90 for the groups. Participants will be divided into two groups as training group and control group. All volunteering children will be included in the study, taking into account the inclusion and exclusion criteria.

Inclusion criteria;

- a. To be in the age range of 6-8,
- b. Being diagnosed with Attention Deficit Hyperactivity Disorder according to the DSM-V criteria,
- c. Continuing school education,
- d. Having agreed to participate in the study after being informed about the research.

Exclusion criteria;

Children with additional physical and neurological problems will be excluded from the study.

4.4. Type of Study: Randomized Controlled Trial

The simple randomization method will be used in this study, and volunteers will be divided into study and control groups at random and with equal probability, taking into account the inclusion and exclusion criteria. For simple randomization, block randomization method will be used.

4.5. Required Manpower for Research:

Dr. Hakan ÖĞÜTLÜ and Prof. Dr. Hakan TÜRKÇAPAR will diagnose patients and direct them for research. The first and second evaluations were blinded by Prof. Dr. Gonca BUMİN will be made Ayres Sensory Integration Therapy be implemented by Büşra KAPLAN, MSc. Büşra Kaplan has a Ayres Sensory Integration Therapy Practitioner Certificate.

4.6. Data Collection Tools of the Research:

Sociodemographic Information Form

Participants' age, gender, time of diagnosis, number of siblings, parental education and employment status, etc. sociodemographic information form which contains the information will be used.

Sensory Profile (SP)

The Sensory Profile (SP) is a family-reported scale that provides data on children's reactions to sensory events in daily life, how sensory behaviors can contribute to performance in daily life, and what difficulties they cause in performance. It consists of 125 questions that can be applied between the ages of 3-10 (18). It has been found that SP effectively distinguishes between typically developing children and children with various developmental difficulties (19). Turkish adaptation study was done by Kayıhan et al. (20).

Sensory Integration and Praxis Test (SIPT)

The Sensory Integration and Praxis Test (SIPT), developed by Ayres, is a standardized performance-based observational test that evaluates sensory perception and sensory perception-based skills in detail in children between the ages of 4 and 8 years and 11 months (21). SIPT is one of the important gold tests in evaluating sensory development and consists of 17 subtests. These subtests provide information on visuospatial perception, visual discrimination, tactile perception, kinesthesia, following verbal instructions, visual motor planning, imitation of body and mouth movements, balance, bilateral coordination, sequencing of movements, and vestibular processing. There is no Turkish reliability and validity study of this test, which evaluates the child's performance, but it is applied by therapists who have international certification in this regard in our country. On the other hand, some studies have suggested that cultural differences do not affect SIPT

scores (22, 23). In our study, it was decided to use SIPT to compare pre-intervention and post-intervention sensory development scores.

Emotion Regulation Checklist (ERC)

The Emotion Regulation Checklist (ERC) is a 24-item scale developed by Shields and Cicchetti to evaluate the emotion regulation competence of children aged 6-13 and can be evaluated by both parents and teachers (24). The items of the scale evaluate affect lability/negativity and emotion adjustment with the items changing on the plot of "never" and "almost always" on a 4-point Likert scale. Its Turkish adaptation was made by Gül Kapçı et al. (25).

Stroop Test TBAG Form (Stroop TBAG)

The Stroop Test TBAG Form (Stroop TBAG) is one of the golden tests used to measure selective attention and ability to shift attention, focusing on the color used in the spelling of the word and the disruptive effect of the color in the pronunciation of the word (26). The test has cards with color names printed in different colors. The form includes yellow, blue, red and green colors and color names. The dimensions of the form consist of four white cards. On the first card, there are black color names on a white background, on the second card, each color name is different from its own color, on the third card there are circles of different colors, and on the fourth card there are neutral words such as "as much, weak, medium" printed with different colors (27). Stroop test TBAG form is applied in five sections. In the first application part, the words written in black on the first card are required to be read. In the second part, the color names It was requested to read in the area where it was written. In the third part, it is required to say the color names of the circles in different colors, in the fourth part the colors of the neutral words printed in different colors, and in the fifth part, using the card in the second part to be read again. It is one of the important cognitive evaluations that evaluates the child in terms of attention and executive functions, with the brain concentrating on two different situations at the same time (26, 27). Turkish standardization of Stroop TBAG in children aged 6-11 was performed by Kılıç et al. (28).

Childhood Executive Functions Inventory (CHEXI)

Childhood Executive Functions Inventory (CHEXI) is a scale consisting of 26 questions for children aged 4-12 years, developed by Lisa B. Thorell and Lilianne Nyberg as a measurement focusing especially on executive functions (29). CHEXI is divided into 4 subgroups: working memory, planning, inhibition and regulation. Questions are answered by parents or teachers. A

rating from 1 to 5 is made according to the accuracy of the statement in each item. It was translated and adapted into Turkish by Ezgi Kayhan (30).

Participation and Environment Scale for Children and Youth (PEM-CY)

The Participation and Environment Scale for Children and Youth (PEM-CY) is a 28-item questionnaire assessing participation in children aged 5-17 years. It is a family-reported scale that questions the child's participation in school, home and society. It is the first survey to question participation in environmental conditions. In the content of the questionnaire, playing games, participating in artistic activities, watching television, school activities, social interaction and participation in household chores are evaluated (31). Turkish validity, reliability and psychometric properties were studied by Kaya Kara et al. (32).

Conners Teacher Rating Scale (CTRS) and Conners Parent Rating Scale (CPRS)

Conners Teacher Rating Scale (CTRS) and Conners Parent Rating Scale (CPRS) are important behavioral screening and diagnostic scales that have a wide range between the ages of 3-17 and are used quite frequently especially in ADHD (33). CTRS consists of 28 items developed to grade students' classroom behaviors by their teachers (34). The normative data of the Turkish translation of the CTRS were obtained, and its validity and reliability were studied (35). CPRS, on the other hand, is a family-reported scale consisting of a total of 48 items, the Turkish adaptation of which was made by Dereboy et al. The questions in the scale are answered by the parents on a 4-point Likert scale (36).

Bruininks-Oseretsky Motor Proficiency Test-2 (BOT-2)

Bruininks-Oseretsky Motor Proficiency Test-2 (BOT-2) is a test developed for children aged 4-21 and developed to measure the motor functions of children. BOT-2 is an observational assessment evaluating motor performance, consisting of 8 subtests and 12 items in total. It consists of fine motor accuracy, fine motor integration, dexterity, bilateral coordination, balance, upper extremity coordination, endurance, speed and agility subtests (37). The Turkish validity and reliability study of the test was performed by Köse et al. (38).

Goal Attainment Scale (GAS)

The Goal Attainment Scale (GAS) is used to evaluate the achievement of functional therapy goals in children receiving treatment in pediatric services. It helps to set priorities and clear goals for

intervention. It provides the child's continuous interest in the set goals and offers a person-centered approach (39). The determined goals should be specific, measurable, achievable, relevant and well-timed (40). While applying GAS, goals are set for the child and possible outcomes are defined for each goal. After a certain intervention, the functional status of the child is determined again. GAS consists of 5 points as -2, -1, 0, +1 and +2. A score of -2 indicates the child's pre-intervention baseline level, a score of -1 indicates a development below the expected attainment level, a score of 0 indicates an expected attainment level, a score of +1 indicates a better-than-expected achievement, and a score of +2 indicates that the child performs much better than expected (39, 40).

4.7. Collection of Data:

The data will be collected by the occupational therapist from the volunteer participants by face-toface interview method, and consent and evaluation forms will be collected.

4.8. Intervention Program:

Individuals will be interviewed for the Informed Consent Form. Consent will be obtained from each individual who volunteers to participate in the study. Consent forms will be given in writing and will be requested back once signed.

Participants signing the Informed Consent Form will form the working group, taking into account the inclusion and exclusion criteria. This study group will be divided into two as training and control groups by simple randomization method. After the training and control groups are determined as a result of randomization, an initial evaluation will be made for all participants separately. Ayres Sensory Integration Therapy will be applied to the training group for 10 weeks, 3 days a week (30 sessions), 60 minutes per session. Final assessments will be made at week 11 of therapy. In the control group; An appointment will be made 10 weeks after the initial assessment. After 10 weeks, final evaluations will be made for control. After the final evaluation, 30 sessions of Ayres Sensory Integration Therapy will be applied for 10 weeks, 3 days a week, similar to the control group. In the Ayres Sensory Integration Therapy application, the therapist will provide interviews with the child and their parents in structured environments, and the parents will be asked to repeat the session by explaining the goals in an explanatory way after the session.

Ayres Sensory Integration Therapy will be administered in accordance with the Ayres Sensory Integration Fidelity Measure (ASI-FM). ASI-FM is a manual protocol based on Ayres Sensory

Integration principles (41). This protocol is applied by certified therapists. Researcher Büşra Kaplan has this certificate, it is attached to the end of the file. In addition, a table related to ASI-FM is given below as an example.

Provide sensory opportunities	Presents the child with opportunities for various sensory experiences, which include tactile, vestibular, and/or proprioceptive experiences; intervention involves more than one sensory modality.
Provide just-right challenges	Tailors activities so as to present challenges to the child that are neither too difficult nor too easy, to evoke the child's adaptive responses to sensory and praxis challenges.
Collaborate on activity choice	Treats the child as an active collaborator in the therapy process, allowing the child to actively exert some control over activity choice; does not predetermine a schedule of activities independently of the child.
Guide self-organization	Supports and guides the child's self-organization of behavior to make choices and plan own behavior to the extent the child capable; encourages the child to initiate and develop ideas and plans for activities.
Support optimal arousal	Ensures that the therapy situation is conducive to attaining or sustaining the child's optimal level of arousal by making changes to environment or activity to support the child's attention, engagement, and comfort.
Create play context	Creates a context of play by building on the child's intrinsic motivation and enjoyment of activities; facilitates or expands on social, motor, imaginative, or object play.
Maximize child's success	Presents or modifies activities so that the child can experience success in doing part or all of an activity that involves a response to a challenge.
Ensure physical safety	Ensures that the child is physically safe either through placement of protective and therapeutic equipment or through the therapist's physical proximity and actions.
Arrange room to engage child	Arranges the room and equipment in the room to motivate the child to choose and engage in an activity.
Foster therapeutic alliance	Respects the child's emotions, conveys positive regard toward the child, seems to connect with the child, and creates a climate of trust and emotional safety.

5. Statistical Analysis of Data:

As descriptive statistics in the study; Frequency (n) and percentage (%) values will be used in the evaluation of categorical variables. Shapiro-Wilk and Kolmogorov-Smirnov normality tests will be used for the conformity of numerical variables to the normal distribution, and as descriptive statistics; Mean±standard deviation values will be given for the variables suitable for normal distribution, and median (minimum-maximum) values will be given for those that do not comply with the normal distribution. The appropriate hypothesis testing method planned to be used in the study was determined as "Two-Way Analysis of Variance with Repetitions on a Single Factor" when parametric test assumptions were met. If the parametric test assumptions for the relevant test are not met, whether there is a difference between the groups in terms of quantitative variables, with the "Student t test" when the parametric test assumptions are met, and with the "Mann-Whitney test" if they are not; In examining whether quantitative variables change according to three separate evaluation times, "Repeated measures variance analysis" will be used when the test assumptions are met, and "Friedman test" if it is not provided. Type I error probability will be taken as $\alpha=0.05$ in all hypothesis tests and SPSS v25.0 package program will be used for statistical evaluations. While calculating the sample size required to test the research hypothesis, the effect widths defined by Cohen* were used and the calculations were made with the G*Power 3.1.9 program.

The minimum sample size required for the study is 90 people in total, approximately equally distributed in the groups that will provide 90% test power at 95% confidence level, with the effect width f=0.30* for "Two-Way Analysis of Variance in Repeated Measurements with Repetitions on a Single Factor".

F tests - ANOVA: Repeated measures, between factors

Analysis: A priori: Compute required sample size

Input: Effect size f = 0.3

 $\alpha \text{ err prob} = 0.05$

Power $(1-\beta \text{ err prob}) = 0.9$

Number of groups = 2

Number of measurements = 2

Corr among rep measures = 0.5

Output: Noncentrality parameter $\lambda = 10,8000000$

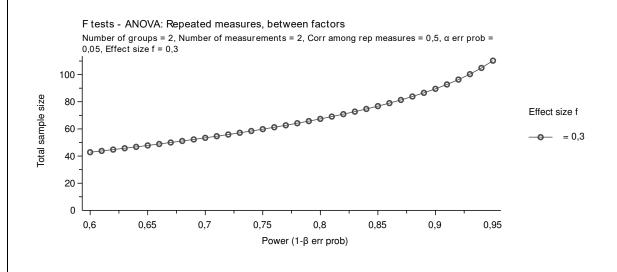
Critical F = 3,9493210

Numerator df = 1,0000000

Denominator df = 88,0000000

Total sample size = 90

Actual power = 0.9015268



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- 7. Ayres Sensory Integration Certificate



Büşra Kaplan

Has Completed the Requirements for the

Certificate in Ayres Sensory Integration.

 $Including \ advanced \ training \ in \ the \ administration, scoring \ and \ interpretation \ of \ the \ comprehensive \ measures \ of \ sensory \ integration, \\ including \ the \ EASI, \ SIPT \& \ SPM.$

CLASI CASI #2007



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Issue Date: January 2023

8. Investigator:

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