

Effectiveness of Combining Medication and Lifestyle Modification with Iranian Traditional Medicine Measures Compared to Medication Alone on the Sleep Quality of Children with Attention-Deficit Hyperactivity Disorder

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Abstract

Background: The current study aims to compare the effects of medication and lifestyle changes with medication alone on the quality of sleep in children with attention deficit hyperactivity disorder.

Method: The study uses a mixed-methods approach to design a treatment for children with ADHD. It employs inductive thematic analysis to identify problems, and create a lifestyle modification package. The package is reviewed and approved by a panel of experts. The study evaluates the effects of two interventions on children with ADHD and sleep problems using a quasi-experimental design. The population consists of 7-11-year-olds from the Felavarjan region, diagnosed with ADHD and experiencing sleep issues. The study involves a combination of drug therapy and lifestyle modification, drug therapy alone, or no intervention.

Results: The findings show that, when compared to the control group, there is a significant difference in sleep quality between the experimental groups that received medication and lifestyle adjustment and those that received medication alone ($P < 0.05$). Children's sleep quality was significantly enhanced by the combination of medicine and lifestyle change, which proved to be more effective than medication alone.

Conclusion: Lifestyle change combined with medication were found to be more effective in improving sleep quality in children with attention deficit hyperactivity disorder compared to medication alone. Based on the findings of the present study, lifestyle modification is suggested as a complementary approach to pharmacotherapy for reducing problems and improving sleep quality in children with attention deficit hyperactivity disorder.

Key Words: Attention Deficit Hyperactivity Disorder, Iranian traditional medicine, Medication, lifestyle, Sleep quality.

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1- INTRODUCTION

Attention Deficit Hyperactivity Disorder (ADHD) is one of the most common pediatric disorders (1). The DSM-5 defines a neurodevelopmental disorder as persistent inattention and hyperactivity-impulsivity, affecting functioning or development, requiring symptoms to appear before age twelve and disrupt daily life (2). This disorder affects around 5% of children under the age of 18 and 2.5% of adults globally. The estimations vary due to the range of methodology used in the studies (3). The prevalence of Attention Deficit Hyperactivity Disorder (ADHD) in Iran varies across provinces, with an average of 8.7%. Differences are due to examination and diagnosing processes, and an increase in incidence is attributed to changing attitudes, awareness, cultural expectations, and living environments (4).

The link between Attention Deficit Hyperactivity Disorder and sleep issues is a significant clinical topic, as sleep disturbances in children with this disorder can exacerbate their symptoms (5). Sleep problems significantly affect the daily life of the child and the family (6-8). Children with this disorder often experience sleep disturbances, daytime drowsiness, and circadian rhythm disorders (9) which may lead to excessive daytime fatigue, mood disorders, attention issues, and behavioral problems, all of which are vital for academic performance and a better quality of life. Children with this disorder experience sleep problems up to 70% compared to 20 to 30% of their healthy peers (10). Sleep problems often lead to daytime sleepiness, which has a substantial impact on children's health, performance, and quality of life (11, 12) and may worsen bad behaviors associated with this disorder (11, 13, 14). Insufficient sleep duration is linked to numerous detrimental health consequences (15). Sleep problems in children with this disorder can be

caused by unhealthy sleep habits (for example, electronic devices in the bedroom, irregular sleep and wake times, exposure to computer blue light late at night, and caffeine use) (11). Sleep disorders may exacerbate problems in children with attention-deficit/hyperactivity disorder, including emotional, social, and adaptive functioning, inattention, hyperactivity, and distractibility (16). Therefore, for the treatment team, it is a significant challenge to identify the cause of sleep disorders and to plan an effective treatment regimen (17).

As a result, managing sleep problems is an important aspect of the overall management of attention deficit hyperactivity disorder in children. Both pharmacological and non-pharmacological interventions are available for treating sleep problems in children with this disorder. When parents are allowed to choose treatments for their children's sleep problems, they primarily prefer non-drug interventions (18). Methylphenidate, a commonly prescribed medication for ADHD, has been linked to adverse neurological and mental effects, causing reduced appetite, anxiety, nausea, headaches, weight loss, and insomnia (19). Around 42% of children with this disease do not respond well to stimulant medications (20), leading to a search for alternative therapies by physicians and parents.

Research on managing sleep disorders in individuals with ADHD is limited, despite extensive studies on the relationship between ADHD and sleep disorders (21). Despite the widespread use of integrative medicine by parents for this disorder, studies reveal varying results, necessitating further research on integrated interventions (22). The study explores the use of lifestyle modifications as a supplement to pharmacotherapy for ADHD, aiming to reduce medication dosage, minimize side

effects, and facilitate quicker discontinuation. Additionally, the lifestyle modification approach can serve as a simple and low-side-effect option, available as a new therapeutic alternative to complement other treatments for parents, child psychologists, and psychiatrists. It compares the effectiveness of a combination of lifestyle modifications and medication with a common treatment, medication alone.

2- MATERIALS AND METHODS

The study design for this research was a mixed-methods (qualitative-quantitative) approach. The first part of the research focused on developing a lifestyle modification package for children using Iranian traditional medicine. A sequential exploratory design based on inductive thematic analysis (data-driven) was used to achieve a network of themes related to the needs and problems of children with attention-deficit/hyperactivity disorder by the research objective. Thematic analysis is a method for identifying, analyzing, and reporting patterns within qualitative data. This method is a process for analyzing textual data and transforms scattered and diverse data into rich and detailed information (23). The research utilized Attride Stirling's thematic analysis method to create a network of themes, presenting basic, organizing, and overarching themes in a map-like format (24). Researchers studied literature and experiences related to children with attention-deficit/hyperactivity disorder, nutrition, inactivity, sleep, media, and lifestyle problems in Iran and the world. They identified problems and assessed needs, developed a program, and designed a package for lifestyle modification. They analyzed traditional Iranian medicine measures and recommendations to find effective interventions for reducing problems, enhancing health, and improving quality of life for children with ADHD. The content validity of the

educational package is assessed by a specialized panel of experts, consisting of 10 faculty members and trusted Iranian medicine graduates. The panel's opinions are collected and analyzed using relative content validity coefficients (CVR) and content validity index (CVI). Panel members' opinions are then rated on a scale of "essential," "useful but not essential," or "not essential," and the results were calculated using a specific formula.

$$CVR = \frac{n_E - \frac{N}{2}}{\frac{N}{2}}$$

n_E is the number of experts who have responded to the essential option, and N is the total number of experts. If the calculated value is greater than the value in the Laush table, the content validity of that item is accepted. The minimum acceptable score for the 10-member panel is 0.62 (25). To determine the CVI, specialists are asked to evaluate each item based on a three-part Likert scale, including "not relevant," "relevant but needs revision," and "fully relevant." The index is calculated by aggregating the agreement scores for each section that received the "relevant but needs revision" and "fully relevant" ratings, divided by the total number of specialists. A score of 0.79 and above is recommended for item acceptance (26). Items that score between 0.7 and 0.79 need to be reviewed, and a score less than 0.7 means the item is unacceptable and will be removed. Ultimately, all session contents were approved by the experts with a score above 0.8.

The research focuses on children diagnosed with Attention Deficit Hyperactivity Disorder at an educational counseling center in Felavarjan. The population includes children with sleep problems and willing mothers. Exclusion criteria include other neurodevelopmental disorders, hyperthyroidism, stimulant use, and simultaneous participation.

Participants were randomly assigned to developed integrated packages, drug therapy with Methylphenidate, or control groups (27). The study aimed to enhance external validity by involving 20 participants in three groups. Mothers completed pre-tests and completed pre-tests for the three groups. The first group received a combination of combined pharmacotherapy and lifestyle modification, while the second group received drug therapy alone. Follow-up questionnaires were completed after one month. Data were analyzed using descriptive and inferential statistical methods, with the control group presented as a summary of the designed package.

2-1. Measures

1) The Swanson, Nolan, and Pelham-4 Scale (SNAP-IV): The SNAP scale, was developed in 1980 as part of the DSM-IV, was rewritten and published in 2001, based on behavioral descriptions of Attention Deficit/Hyperactivity Disorder (28). The short form of the scale consists of 26 questions scored on a 4-point scale, identifying predominantly inattentive, hyperactive-impulsive, and oppositional defiant types. The compound form uses the same questions. A score higher than 1.78 in the attention deficit, hyperactivity, oppositional defiant, and combined subscales indicates ADHD (29). The SNAP-IV scale, standardized in Iran for children aged 7-12, has high criterion validity, reliability, and Cronbach's alpha. It significantly distinguishes children with ADHD from those without the disorder. The scale's internal consistency and temporal reliability are high, with Pearson correlation coefficients ranging from 0.68 to 0.77. The 18-question short form is used in this research (30).

2) The Children's Sleep Habits Questionnaire (CSHQ): This questionnaire was developed by Owens, Spirito, and McGuinn in 2000 to assess the quality and habits of children's sleep in 45 items. The

questionnaire is designed for children aged 4 to 12 and is completed by one of the parents. The items are conceptually grouped into eight subscales: sleep resistance, sleep onset delay, sleep duration, sleep anxiety, nighttime awakenings, parasomnia, sleep-related breathing disorders, and daytime sleepiness. The questionnaire is scored on a 5-point Likert scale. Some questions in these questionnaires have diagnostic and therapeutic value, not research value; therefore, only 33 of the questions are considered in scoring. Each item has a value between 1 to 3 (from rare to common), except for items (1, 2, 3, 10, 11, 26) which are scored inversely. The range of scores is between 99-33. The score of each subscale is obtained from the sum of the mentioned questions. Resistance to sleep (1,3,4,5,6,8) has a minimum score of 6 and a maximum score of 8 in this component. Delay in sleep onset has a minimum score of 1 and a maximum score of 3 in this component, while sleep duration (9, 10, 11) has a minimum score of 3 and a maximum score of 9 in this component. Sleep anxiety (5,7,8,21) has a minimum score of 4 and a maximum score of 12 in this component. Night awakenings (24, 25, 16) have a minimum score of 3 and a maximum score of 9 in this component. Parasomnia (12, 13, 14, 15, 17, 22, 23) has a minimum score of 7 and a maximum score of 21 in this component. Sleep-related breathing disorders (18, 19, 20) have a minimum score of 3 and a maximum score of 9 in this component, while daytime sleepiness (26, 27, 28, 29, 30, 31, 32, 33) has a minimum score of 8 and a maximum score of 24 in this component. The total sleep problems score is the sum of the scores of all subscales, and the score of each subscale is the sum of the scores of the items related to that component. Higher scores on the sleep habits questionnaire indicate more sleep problems and lower sleep quality. The estimate of internal consistency

(Cronbach's alpha) for the subscales was 0.70 in a non-clinical sample of children aged 4 to 10 years. The reliability estimate using the two-week retest method ranged from 0.62 to 0.79 (31). In Iran, the validity of the tool has been evaluated using the content validity method, and its reliability has been determined through a test-retest

method with a two-week interval for 10 children aged 6 to 11 years, with a reliability coefficient of 0.97(32). The Cronbach's alpha coefficient of the questionnaire was obtained as 0.77 and 0.79 in two studies (33).

3- RESULTS

Table-1: Demographic Characteristics.

variable	class	experimental group1 (Combination package of lifestyle modification and drug therapy)		experimental group 2 (Medication alone)		group control	
		Frequency	percentage	Frequency	percentage	Frequency	percentage
Child's gender	boy	7	35	9	45	9	45
	girl	13	65	11	55	11	55
Age of child	7	4	20	7	35	4	20
	8	5	25	5	25	2	10
	9	4	20	2	10	6	30
	10	5	25	6	30	6	30
	11	2	10	0	0	2	10
Father's education	Undergraduate and Diploma	16	80	15	75	17	85
	Bachelors and Masters	4	20	5	25	3	15
Mother's education	Undergraduate and Diploma	16	80	14	70	17	85
	Bachelors and Masters	4	20	6	30	3	15
Father 'job	worker	1	5	1	5	5	25
	employee	1	5	5	25	3	15
	Freelance job	15	75	14	70	12	60
	Retired	1	5	0	0	0	0
	military	2	10	0	0	0	0
Mother 'job	housekeeper	17	85	12	60	15	75
	Freelance job	1	5	2	10	5	25
	employee	2	10	6	30	0	0

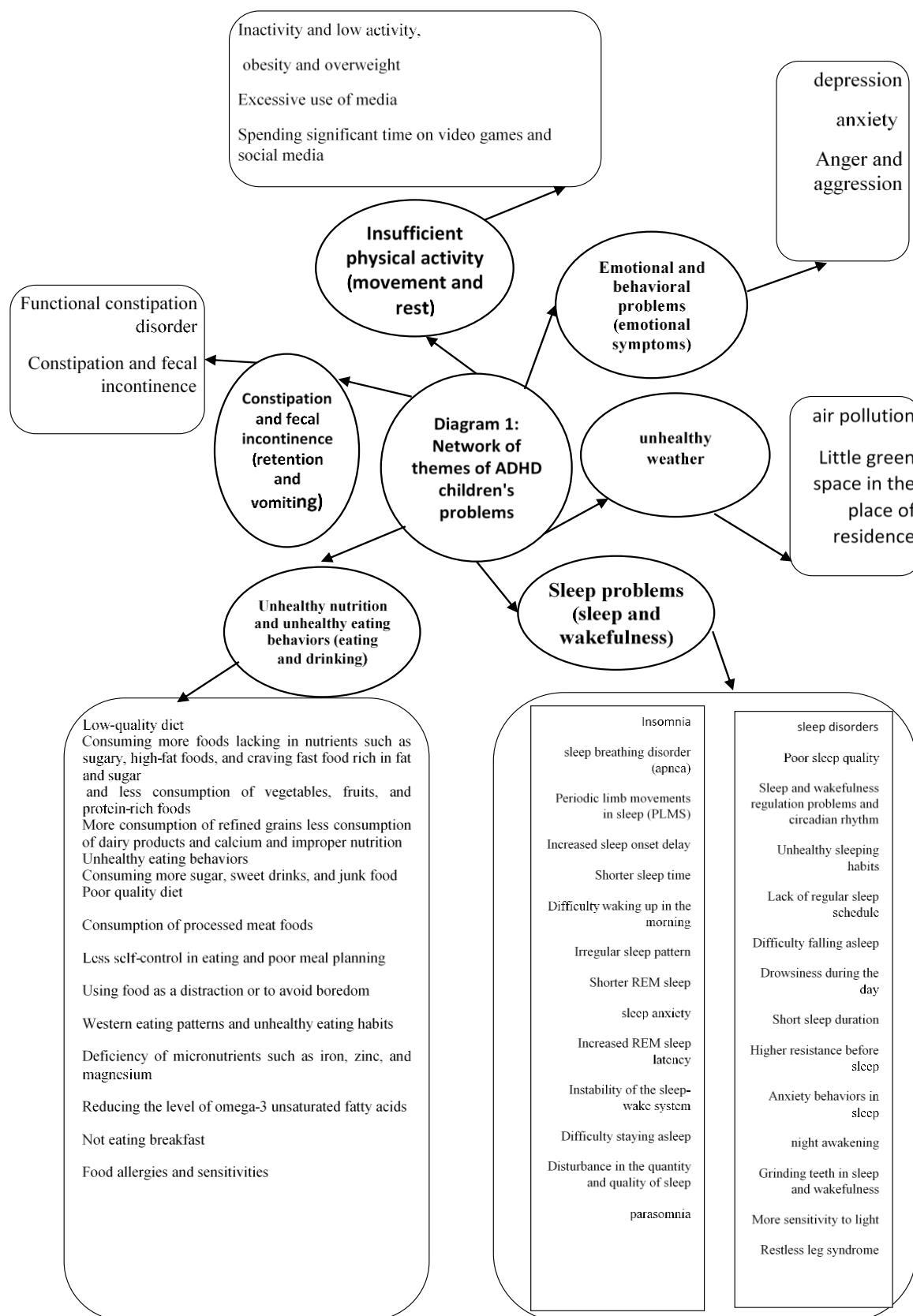


Figure-1: Network of themes of ADHD children's problems.

Table-2: Suggested program for children with attention deficit hyperactivity disorder.

Six principles of a healthy lifestyle (the essential six)	Proposed program
1) Weather	Presence in nature and green spaces with clean air (34), (35), (36)
2) Movement and stillness	Choosing a sport that suits the child's temperament, interests, and age (people with a hot and dry temperament should avoid doing heavy sports such as volleyball, football, wrestling, etc. for a long time because they increase blood bile, aggression, and restlessness, or doing these sports with special precautions); instead, doing light sports such as Pilates, walking, swimming, darts, and table tennis, etc (37). Types of suitable exercises: -Moderate-intensity aerobic activity (38,39), - Rhythmic exercises with music (40), -swimming (41-43).
3) Sleep and wakefulness	Traditional Iranian medicine measures to improve sleep problems: A) Following the principles of sleep hygiene recommended by Iranian medicine sources :Having a regular sleep schedule (44) :Sleeping between 10 pm and 2 am, when growth hormone secretion is highest - Not sleeping with a full and heavy stomach (45) - Bathing and footbathing with hot water - Suitable environmental conditions (healthy air, moderate temperature, away from noise, high humidity and unpleasant odors, not sleeping in a bright place) -Emphasis on avoiding daytime sleepiness in most temperaments(45). b) Foot massage, c) Using calm and pleasant music and natural sounds such as running water in sleep hygiene, d) Sleeping foods before bed and suitable herbal medicines for treating insomnia (46). e) Aromatherapy .(14, 15)(16)
4) Eating and drinking	Differences in human temperaments from the perspective of traditional Iranian medicine and the need to identify each person's temperament and recommend a suitable diet and advice to avoid certain foods to moderate the temperament (47). Traditional Iranian medicine measures for hyperactive children: A) Eating breakfast, B) Including saffron as a natural stimulant in the diet (48,49). C) Avoidances: (Consumption of certain substances should be avoided for a specific period and varies from person to person). - Avoid excessive consumption of spices (spicy, sour, salty foods, spicy foods that contain pepper); Avoid foods such as lentils, raw garlic and onions, mushrooms, eggplant, cabbage, beef, veal, camel and ostrich; Avoid consumption of foods containing colors and unnatural substances and artificial preservatives (50-53)

5) Excretion of unnecessary substances from the body (retention and vomiting)	A) Lifestyle changes as the first intervention for constipation: -Protecting children from extreme cold and extreme heat -A diet appropriate to the age and temperament of the individual, -Moderate intensity exercise, -Appropriate sleep duration based on the temperament of the child, -Uplifting and funny stories for the child and a stress-free living environment and easier bowel movements in the child:(54) (55,56) (57)
6) Emotional symptoms	Traditional medicine measures to manage anxiety and low mood and create happiness and peace in hyperactive children: -Play plays a very important role in a child's physical and mental development, reducing anxiety and depression, and increasing happiness (58,59) - Foot massage before bed and reducing behavioral problems and anxiety (60-62)

Table-3: A brief description of the child's lifestyle modification sessions by purpose, content, and tasks of each session.

Session number	The title of the session	purpose	Content and topics of educational topics	Homework
1	Hyperactivity and attention deficit and the six principles of health	Acquainting mothers with attention-deficit/hyperactivity disorder, the causes and symptoms of this disorder, and general familiarity with the six principles of health to modify lifestyle.	<ol style="list-style-type: none"> 1) Getting to know the members of the group and giving a brief explanation to the parents about the children's problems. 2) Explanation of attention-deficit/hyperactivity disorder, the cause and symptoms of this disorder. Explanation of the prevalence of sleep problems in these children. 3) A brief description of traditional Iranian medicine, measures, and six principles of health (essential), and its use for lifestyle modification 4) General explanation about the process of the meetings and the general headings of the meetings. 5) Explaining about group rules and compiling group rules Summary of the meeting	Reviewing the contents of the first session until the next session and writing the child's problems in the field of nutrition, sleep, using the phone and watching TV, activity and sports, digestive problems, anxiety, and mood.
2	Weather and attention deficit hyperactivity disorder	Getting to know more about the six principles of health to improve the lifestyle and familiarity with the principle of climate and suggested programs based on research.	<ol style="list-style-type: none"> 1) review of the previous meeting Examining assignments and providing feedback <ol style="list-style-type: none"> 2) Describing and defining the six principles of health in more detail and expressing the effects of observing these principles in the management of various physical and mental disorders (47). 3) Familiarity with the first principle (climate) and proposed programs related to this principle according to researches 4) The proposed program is based on this principle: Planning to go to the park, mountain climbing, and green spaces: walking at least half an hour a day in the park, planning to be in nature and play in nature for at 	Reviewing the materials until the next meeting and planning for the child to play and walk in nature and green spaces on weekdays and if it is not possible, plan to play in nature at least on the weekend.

			least a week (63-66).	
3	Exercise and hyperactivity and attention deficit	Acquaintance with the principle of movement and stillness and the proposed programs related to research and informing mothers about the negative effects of sleep problems on the child's performance	<p>Review of the previous session</p> <p>Examining assignments and providing feedback</p> <p>Getting to know the principle of motion and stillness and the proposed program related to this principle according to research</p> <p>1) Choosing the right sport according to the child's mood and interest (37).</p> <p>Explanation of the recommendations of Iranian medicine regarding the choice of exercise.</p> <p>Acquaintance with suitable sports for hyperactive children according to research, includes aerobic activity, aerobics, rhythmic movements with music, balance exercises, yoga, basketball, gymnastics, and swimming.(67-70 ,38-43)</p> <p>2) Using massage to improve children's symptoms and problems:</p> <p>A) Using massage alone (71)..</p> <p>b) Massage therapy as a supplement to drug therapy to improve symptoms, increase attention, and reduce hyperactivity (61,48)</p> <p>Setting the rest and rest program includes:</p> <p>A) Watching TV, and playing games with phones and computers is planned and managed for a maximum of one to two hours a day.</p> <p>b) Explanation of the principle of sleep and wakefulness and the effects of sleep problems on the exacerbation of hyperactivity disorder in children (48,72)</p>	<p>the Browsing contents until the next session and enrolling in the favorite sports class that suits the child's temperament and ability.</p> <p>2) Using massage as a supplement to drug treatment</p>
4	Sleep and hyperactivity and attention deficit	Getting to know the principle of sleep and the principles and measures of sleep hygiene in traditional Iranian medicine	<p>Reviewing the contents of the previous session and explaining more about the types of sleep problems in hyperactive children</p> <p>Overview of Iranian traditional medicine measures to improve sleep problems:</p> <p>1) Compliance with the principles of sleep hygiene recommended by Iranian medical sources (44-46)</p> <p>2) aromatherapy (73)</p> <p>Summarize the meeting</p>	<p>1) Adhering to the principles of sleep hygiene for the child and adhering to a regular sleep schedule on all days of the week, even on non-holiday days.</p> <p>2) Using a scent suitable for the child's mood to create a sense of relaxation and comfortable sleep for the child</p>
5	Eating and	Familiarity with the	Reviewing the previous session and summarizing the subject of sleep measures in	Review the contents until

	drinking and hyperactivity and attention deficit	principle of eating and drinking and measures of Iranian traditional medicine in this field in hyperactive children	<p>traditional medicine</p> <p>Examining assignments and providing feedback</p> <p>Getting to know the principles of eating and drinking and the proposed program according to</p> <p>Iranian traditional medicine measures for hyperactive children:</p> <ol style="list-style-type: none"> 1) Eating breakfast 2) Placing saffron as a natural stimulant in the food plan(49 ,48) 3)Abstinence (the consumption of certain substances should be avoided for a certain period and it varies from person to person(. 4)Table of suggestions for healthy and balanced meals (breakfast, lunch, dinner, and drinks) based on traditional Iranian medicine. (55, 60-63) 	<p>the next meeting.</p> <p>Using the table of food suggestions to include healthy and recommended foods in the child's meal plan.</p> <p>Saffron should be included in the child's diet in different ways and in the way that the child likes.</p>
6	Retention and vomiting, hyperactivity and attention deficit, emotional symptoms, and hyperactivity and attention deficit	Familiarity with the principle of retention and vomiting as well as physical symptoms and solutions of Iranian traditional medicine in this field	<p>Review the contents of the previous session</p> <p>Examining assignments and providing feedback</p> <p>Getting to know the principle of removing unnecessary substances from the body (retention and vomiting)(47)</p> <p>Children with ADHD are significantly more prone to constipation followed by fecal incontinence (74,75).</p> <p>Familiarity with interventions of Iranian traditional medicine in the field of children's constipation:</p> <ol style="list-style-type: none"> 1) Lifestyle changes are considered the first intervention for constipation. Compliance with these six essential principles has an important effect on children's constipation (51,56,57,76). 2) The second solution is to prescribe oral laxatives based on the child's condition and temperament (74, 75) . 3) The third solution is to use suppositories and topical medicines (56) 4) Familiarity with the principle of emotional states and symptoms <p>Familiarity with measures to manage anxiety and low mood in children and increase happiness and peace (77)</p> <ol style="list-style-type: none"> 1) Relaxing massage to improve mood and behavior (71,78) 2) Reducing behavioral problems and anxiety by massaging the soles of the feet before going to bed (60-62) 3) Exercise and play to reduce anxiety and depression of the child and increase happiness (58,59) 	<p>Browsing content</p> <p>In case of constipation, the recommended measures should be used to solve the child's problem.</p> <p>Placing games and sports as part of the child's daily schedule</p> <p>Trying to establish a positive relationship with the child with soothing body and foot massages in times of anxiety and before sleep</p> <p>Storytelling before sleep</p>

			Story therapy to reduce behavioral incompatibility and increase the psychological health of hyperactive children (79) Summarize the meeting	
7	Summary and review	Reviewing the contents of all meetings and providing solutions to maintain positive changes in the child's lifestyle	Examining assignments and providing feedback Summarizing and reviewing the contents of all meetings and stating the importance of adhering to the principles of the essential set and its role in improving the symptoms of hyperactivity Getting feedback from mothers on the implementation of the principles Questions answers and answers to mothers' concerns and problems Providing solutions for mothers to maintain the changes in lifestyle Summarize the meeting.	

Table 4 results show that the mean scores of sleep problems and their dimensions (resistance to sleep, delayed sleep onset, sleep duration, sleep anxiety, nighttime awakening, parasomnia, sleep-disordered breathing, daytime sleepiness) decreased in the post-test and follow-up compared to the pre-test phase.

To assess normality of sleep quality scores and their dimensions, parametric tests were used, specifically the Kolmogorov-Smirnov test. The results indicated that the sleep quality scores and their dimensions in children with ADHD have normal distributions ($P > 0.05$). Levene's test was used to test the equality of variances of sleep quality scores and their dimensions. The F values for sleep quality, resistance to sleep, delayed sleep onset, sleep duration, sleep anxiety, nighttime awakening, parasomnia, sleep-disordered

breathing, and daytime sleepiness were 0.347, 2.732, 0.935, 0.888, 2.715, 1.696, 1.713, 2.739, and 2.321, respectively. The results showed that the variances of sleep quality scores and their dimensions in children with ADHD were equal ($p > 0.05$).

Mauchly's test was conducted to test the sphericity of the covariance matrices of sleep quality variables and their dimensions. The results indicated that the covariances or relationships between sleep quality scores and their dimensions in children with ADHD, except for the nighttime awakening variable, were not consistent with the unit matrix. This assumption was tested and not confirmed ($p > 0.05$). Based on these results, the use of parametric tests in the pre-test, post-test, and follow-up phases is appropriate.

Table-4: Comparison of mean and standard deviation of sleep problem scores and its dimensions in children with attention deficit/activity disorder with sleep problems in the pre-test, post-test, and follow-up stages.

Statistical indicator	Test Type	experimental group1 (Combination package of lifestyle modification and drug therapy)		experimental group 2 (Medication alone)		control	
		Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
sleep problems	pre-test	65/80	6/59	74/40	6/65	63/70	6/21
	Post-test	55/80	7/34	72/60	6/18	63/65	6/48
	follow up	52/10	5/32	70/10	5/59	64/65	6/39
Resistance to sleep	pre-test	12/70	2/55	13/15	1/69	10/90	1/97
	Post-test	11/20	2/23	13	1/48	10/90	1/83
	follow up	10/35	1/84	12/60	1/23	11/05	1/79
Sleep onset delay	pre-test	1/85	0/87	2/55	0/51	2/35	0/58
	Post-test	1/65	0/58	2/70	0/47	2/30	0/57
	follow up	1/45	0/51	2/70	0/47	2/35	0/58
sleep duration	pre-test	6/60	1/50	8/10	1/48	6/70	1/71
	Post-test	5/80	1/19	8/15	1/34	6/80	1/73
	follow up	5/60	1/23	8/10	1/41	6/90	1/65
sleep anxiety	pre-test	8/65	2	9/05	1/31	6/55	1/90
	Post-test	7/35	1/78	8/75	1/29	6/55	1/95
	follow up	7/05	1/35	8/35	0/87	6/60	1/90
night awakening	pre-test	4/60	1/27	3/35	0/93	4/70	0/86
	Post-test	4	1/48	5/45	0/99	4/65	0/87
	follow up	3/45	0/82	5/50	1/27	4/70	0/92
Parasomnia	pre-test	11/45	2/30	13/55	2/08	11/15	1/56
	Post-test	9	1/48	13	1/97	11/30	1/52
	follow up	8/50	1/27	12/45	1/98	11/40	1/60
Sleep-disordered breathing	pre-test	4/30	1/55	4/65	1/78	4/50	1/23
	Post-test	4/15	1/26	4/55	1/57	4/55	1/27
	follow up	4/15	1/26	4/50	1/39	4/55	1/27
Daily sleepiness	pre-test	15/65	3/74	18	1/65	16/85	2/92
	Post-test	12/65	2/56	17	1/62	16/60	3/01
	follow up	11/55	2/01	15/90	1/88	17/10	3/17

As indicated in Table 5, the factor "test" had a significant impact on sleep quality, meaning there were significant differences in sleep quality between the pre-test, post-test, and follow-up. The interaction between the "test" and "group membership" factors was also significant, indicating that sleep quality varied significantly across the three-time points

(pre-test, post-test, and follow-up) depending on group membership (combined lifestyle modification and pharmacotherapy package, pharmacotherapy alone, and control group). Table 4 displays the outcomes of the repeated measures ANOVA for the within-subjects factor (pre-test, post-test, and follow-up) and the interaction of the

within-subjects and between-subjects factors (combined lifestyle modification and pharmacotherapy package,

pharmacotherapy alone, and control group) for the sleep quality variable.

Table-5: Results of multivariate tests in the repeated measures ANOVA for sleep quality.

effect		value	F	Model df	Error df	Sig
test	Pillai's Trace	0/722	72.554	2	56	0.001
	Wilks' lambda	0/278	72.554	2	56	0.001
	Hotelling's trace	2/591	72.554	2	56	0.001
	Roy's Largest Root	2/591	72.554	2	56	0.001
group*Interaction test	Pillai's Trace	0/818	19/728	4	114	0.001
	Wilks' lambda	0/236	29.693	4	112	0.001
	Hotelling's trace	3/018	41/494	4	110	0.001
	Roy's Largest Root	2/940	83.797	2	57	0.001

Table-6: Results of the repeated measures ANOVA for the within-subjects factor and the interaction of the within-subjects and between-subjects factors for the sleep quality variable.

Source of variation	Type of analysis	The sum of squares (SS)	Df	Mean squares (MS)	F-ratio	Sig.	Eta-squared (η^2)	Power of the test
Test	Sphericity Assumed	1018/144	2/000	509/072	71/982	0.001	0/558	1/000
	Greenhouse-Geisser	1018/144	1/738	585/748	71/982	0.001	0/558	1/000
	Huynh-Feldt	1018/144	1/851	550/039	71/982	0.001	0/558	1/000
	Lower-bound	1018/144	1/000	1018/144	71/982	0.001	0/558	1/000
Interaction test*group	Sphericity Assumed	1190/289	4/000	297/572	42/076	0.001	0/596	1/000
	Greenhouse-Geisser	1190/289	3/476	342/392	42/076	0.001	0/596	1/000
	Huynh-Feldt	1190/289	3/702	321/519	42/076	0.001	0/596	1/000
	Lower-bound	1190/289	2/000	595/144	42/076	0.001	0/596	1/000

As shown in Table 6, the results based on Greenhouse-Geisser ($F = 982/71$, $df = 738/1$, $P > 0.01$) indicate a significant difference ($P > 0.01$) in sleep quality between the pre-test, post-test, and follow-

up. The partial eta squared for the 'test' factor is 0.558, and the power of the test is 1.000. This result shows that 55.8% of the difference in sleep quality between the pre-test, post-test, and follow-up is related to

the independent variable (the combined intervention of lifestyle modification and medication, and medication alone), which is confirmed with 100% power.

Additionally, there is a significant interaction between the 'test' and 'group' factors (experimental group: combined intervention of lifestyle modification and medication, medication alone, and control group) in terms of sleep quality based on Greenhouse-Geisser results ($F = 42.076$, $df = 3.476$, $P > 0.01$). This means that there is a significant difference between the pre-test, post-test, and follow-up in the experimental group (combined intervention of lifestyle modification and medication, medication alone) and the control group. The partial eta squared for the interaction of 'test' * 'group membership' (experimental and control) is 0.596, and the power of the test is 1.000. This result indicates that 59.6% of the difference between the experimental group (combined intervention of lifestyle modification and medication) and the

control group in sleep quality is related to the independent variable, which is confirmed with 100% power.

As shown in Table 7, there is a significant difference ($P > 0.01$) between the groups in terms of sleep quality scores among the studied methods. The difference in sleep quality scores between children with Attention Deficit Hyperactivity Disorder (ADHD) and sleep problems in the combined lifestyle modification and medication group and the control group is significant.

The results show that the adjusted mean sleep quality scores in all groups decreased from the pre-test to the post-test phase, and then decreased slightly further in the follow-up phase.

Table 9 results indicate that there is a significant difference between pre-test sleep quality scores and post-test and follow-up sleep quality scores. A significant difference was also observed between post-test and follow-up sleep quality scores within the groups.

Table-7: between-subjects effects based on repeated measures ANOVA for children's sleep quality scores in the study groups."

	Sum of squares(SS)	df	Mean square (MS)	F	Significance level (p-value)	Eta squared (η^2)	Statistical power
method	6329/911	2	3164/956	29/786	/000	0/511	1/000
Error	6056/667	57	106/257				

Table-8: Comparison of Post-Test and Follow-up Sleep Quality Scores (Over Time).

Standard Deviation	Adjusted mean	time
0/838	67/967	Pre-test
0/864	64/017	Post-test
0/747	62/283	Follow- up

Table-9: Pairwise Comparison of Sleep Quality Scores at Pre-test, Post-test, and Follow-up in the Experimental Groups (Time).

Time	Time	Means difference	sig
Pre-test	Post-test	3.950*	0.001
	Follow-up	5.683*	0.001
Post-test	Follow-up	1.733*	0.001

The adjusted mean sleep quality scores presented in Table 10 reveal a statistically significant difference between the experimental groups (combined lifestyle modification and pharmacotherapy, and pharmacotherapy only) and the control group.

Results from Table 11 indicate a significant difference in sleep quality scores between the experimental groups (combined lifestyle modification and pharmacotherapy, and pharmacotherapy alone) and the control group. This difference favors the experimental groups, suggesting that both combined lifestyle

modification and pharmacotherapy alone were effective in improving sleep quality in children with ADHD and sleep problems. Moreover, there was a significant difference ($p < 0.05$) between the combined lifestyle modification and pharmacotherapy group and the pharmacotherapy alone group, indicating that the combined intervention led to further improvement in sleep quality. The negative difference in mean scores suggests that the combined intervention group experienced fewer sleep problems compared to the pharmacotherapy-only group.

Table-10: Comparison of Sleep Quality Scores Among Study Groups.

Groups	Adjusted mean	Standard Deviation
Experimental group: Lifestyle modification and pharmacotherapy	57/900	1/331
Experimental group: Pharmacotherapy alone	72/367	1/331
control	64/000	1/331

Table-11: Pairwise Comparison of Sleep Quality Scores in Children with ADHD and Sleep Problems Between Experimental and Control Groups.

Group	group	Means difference	sig
Lifestyle modification and pharmacotherapy	Pharmacotherapy alone	-14.467*	0.001
Lifestyle modification and pharmacotherapy	control	-6.100*	0/006
Pharmacotherapy alone	control	8.367*	0.001

4- DISCUSSION

This research was conducted to compare the effectiveness of combining medication and lifestyle modification with medication alone on the sleep quality of children with attention-deficit/hyperactivity disorder who have sleep problems. The results of the study showed that both treatment groups, medication alone and combined with lifestyle modifications, were effective in reducing sleep problems and improving sleep quality. The combination of

medication and lifestyle modifications was more effective than medication alone in reducing sleep problems and improving sleep quality in children with ADHD. The difference in average sleep problem scores between these two groups was statistically significant ($p < 0.05$). Based on the results, it can be concluded that a combination of medication and lifestyle modifications is a more effective approach for reducing sleep problems and improving sleep quality in children with ADHD. These results highlight the importance of an integrated approach to ADHD treatment.

Pharmacological management is often used alongside behavioral and non-pharmacological interventions. Sleep disorders and ADHD may be related to similar causes, particularly disruptions in dopaminergic and melatonergic pathways. Some medications, such as stimulants prescribed to alleviate symptoms of ADHD/impulsivity or other medications used to manage co-occurring psychiatric symptoms like anxiety, can potentially disrupt and prolong sleep duration in children (80-82). A high dose of methylphenidate (Ritalin) has been associated with an increase in sleep-related problems, especially among those with lower weight or BMI (83).

In the field of pharmacological management of sleep problems in attention deficit hyperactivity disorder, medications have been used. Melatonin treatment studies show that in children with ADHD, the use of melatonin is associated with increased sleep duration and reduced sleep onset latency. Although long-term use of melatonin is considered safe for children with ADHD (84, 85), reported side effects of this medication include bedwetting, headaches, night terrors, daytime drowsiness, stomach pain, or constipation (86). Other studies related to the drug clonidine in children with ADHD have shown a reduction in sleep delay during nighttime awakenings. Clonidine is classified as an alpha agonist. Side effects of clonidine may include severe sedation at night, morning fatigue, rebound awakening, early morning awakening, and inability to return to sleep. Furthermore, a study has reported that in children with ADHD and increased motor symptoms during sleep who have low ferritin levels, iron supplementation could be beneficial (87).

Additionally, studies have linked exercise with better sleep, so providing a sports intervention for children with ADHD could be beneficial (88, 89) Higher-

intensity sports interventions should be offered to improve sleep quality. Physical activity can improve sleep efficiency, sleep onset latency, and wakefulness after sleep onset (90, 91). Evidence shows that engaging in regular physical activity is associated with improved sleep problems (88). Participating in physical activity and exercise may facilitate sleep regulation. These changes stimulate body temperature and lead to the production of melatonin before sleep, resulting in subsequent changes in body temperature regulation during the sleep cycle (92). The increase in body temperature during exercise leads to an increase in melatonin production, which results in a reduction in the time needed to fall asleep and an improvement in the quality and quantity of sleep (93).

It seems that lifestyle modification, as a complement to medication, enhances the effectiveness of treatment. Lifestyle changes may help improve sleep quality through factors such as establishing a regular sleep routine, reducing environmental stimuli before bedtime, and enhancing sleep hygiene. In the context of lifestyle modification in children with Attention Deficit Hyperactivity Disorder (ADHD) and its effects on improving behaviors and health outcomes in these children, the results of this study align with the findings of Ulla, Gonzalez, Tran, Tyler, Sasser, and colleagues (2021) titled "Feasibility and Acceptability of the LEAP Lifestyle Improvement Program: A New Behavioral Management Training Program for Parents of Children with ADHD." The findings indicated that the LEAP program is an acceptable intervention model for promoting physical activity among parents and their children with ADHD. This study showed that LEAP, a new intervention to help families of children with ADHD make healthy lifestyle changes related to physical activity, sleep, and media use, is feasible and highly acceptable. This intervention is a promising approach to

improving behaviors and health outcomes in children with ADHD and has implications for enhancing ADHD behavioral treatment. Such a method could herald improvements in the long-term health and well-being of children with ADHD.

Lifestyle modifications can help reduce medication dosages and adverse effects in children with ADHD. Organizations like the American Academy of Sleep Medicine (AASM) and the American Psychiatric Association (APA) recommend holistic treatment, including lifestyle changes and medication. Poor sleep hygiene, such as maintaining regular sleep and wake schedules, limiting electronic devices, reducing exposure to blue light, and creating a calm environment, can improve sleep quality. Traditional medical measures can also positively impact sleep quality. The effectiveness of these interventions may be attributed to lifestyle modifications that allow medications to work more effectively.

The study suggests a comprehensive therapy approach that combines medicine and lifestyle changes for ADHD. Parents and Psychiatrists should receive training on lifestyle modifications and strategies for improved sleep. Individual characteristics, age, symptom severity, and comorbid conditions should be considered when choosing treatment. Further research is needed to compare interventions.

Questions for future research could include what kinds of lifestyle change therapies have the biggest effects on enhancing sleep in children with ADHD could be a topic for future studies. How long does it take for medications and lifestyle modifications to fully take effect? Do different subgroups of children with ADHD respond differently to this treatment? Why do some children react better to a combination of treatments? The limitations of this study include the fact that it only represents a sample of the literature in this area and that

its findings may not apply to other research projects. Children with ADHD may also have sleep issues due to other reasons that were not looked at in this study.

5- CONCLUSION

According to the study's findings, a potential therapy strategy for improving sleep quality and reducing sleep problems in children with ADHD may involve a mix of medication and lifestyle changes. To provide more accurate recommendations, further study in this field is necessary.

6- ETHICAL CONSIDERATIONS

This article is a part of a PhD thesis and has been approved by the Research Ethics Committee of Khomeini Shahr Azad University with the ID IR.IAU.KHSH.REC.1402.10.1.

7-CONFLICT OF INTEREST

The authors have declared that they have no potential conflicts of interest regarding with respect to the research, authorship, and publication of this article.

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