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A Comparison of Combined Methylphenidate with Common Figs and Almond Syrup, Methylphenidate with Sweet Almond Syrup, and Methylphenidate with Placebo Syrup in the Treatment of Children and Adolescents with ADHD: A Randomized, Double-Blind, Parallel-Group Clinical Trial

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Abstract

Background: One of the most common health disorders among children is attention deficit/hyperactivity disorder (ADHD). Some patients do not respond to current treatments or are unable to tolerate their side effects. In Persian medicine, both sweet almonds and figs are brain tonics and are helpful for neurological diseases. This study aimed to evaluate the efficacy of fig and sweet almond syrup on children with ADHD.

Methods: The patients with ADHD (age 6 to 14 years) were randomly assigned to 3 groups. All groups received the standard drug methylphenidate. The first group (A) received almond and fig syrup, the second group (B) received sweet almond syrup, and the third group (C) received a placebo syrup. The outcomes were assessed using a short and revised version of the Connors Rating Scale (CPRS-R-S) and the Parent ADHD Rating Scale every 4 weeks for 12 weeks.

Results: This study showed that, based on the CPRS-R-S, cognitive problems/inattention scores changed from baseline to week 12 in group A (10.87 ± 5.06 to 6.55 ± 2.63), group B (11.57 ± 3.52 to 6.20 ± 2.28), and group C (8.05 ± 5.22 to 8.10 ± 3.56). Significant improvement was observed in groups A and B ($P = 0.009$).

Conclusion: This study found that a syrup combining figs and sweet almonds may serve as a complementary treatment for children with inattentive ADHD. When used alongside methylphenidate, the syrup significantly improved inattention and cognitive/attention difficulties.

Keywords: Attention Deficit Hyperactivity Disorder, Complementary Medicine, *Ficus carica*, Persian Medicine, Sweet Almond

Conflicts of Interest: *None declared*
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Introduction

Attention-deficit hyperactivity disorder (ADHD) is considered one of the neurodevelopmental disorders in child-

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↑What is "already known" in this topic:
Attention-deficit hyperactivity disorder (ADHD) is considered one of the neurodevelopmental disorders in childhood and adolescence. The most common type of medication for ADHD is stimulant medication. Methylphenidate (Ritalin) is the most widely used. However, drug side effects and resistance to Ritalin treatment necessitate the need to find other treatments.

→What this article adds:
Both sweet almonds and figs are considered brain tonics and are beneficial for neurological diseases. The results of this study indicate that Tinlose syrup (a combination of figs and sweet almonds) can be an effective and safe complementary and alternative medicine in the adjuvant treatment of childhood ADHD.

hood and adolescence. The incidence of ADHD is 7.6% in children aged 3 to 12 years and 5.6% in adolescents (1). According to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), the symptoms of this disorder are characterized by inattention, hyperactivity, and impulsivity, which are usually associated with emotional disorders, cognitive disorders, and psychiatric illnesses (2). Several factors are effective in causing this disorder, such as genetic, environmental, neurobiological, and psychosocial factors (2). Neurotransmitters such as dopamine and norepinephrine play an essential role in hyperactivity (3). The dopaminergic pathway is critical in the pathogenesis of ADHD (3). Based on studies, oxidative stress plays a critical role in the development and occurrence of ADHD symptoms (4) and low levels of copper (Cu), iron (Fe), zinc (Zn), magnesium (Mg), and omega-3 fatty acids have been found in children with ADHD (3).

The most common type of medication for ADHD is stimulant medication. Methylphenidate (Ritalin) is the most widely used (5). Methylphenidate increases dopamine and norepinephrine levels. Common side effects of methylphenidate include sleep disturbance, decreased appetite, dry mouth, anxiety, and weight loss (6) and also psychosis, allergic reactions, substance abuse, and cardiovascular problems (7). Therefore, it is necessary to find other effective and less complicated treatments.

The use of complementary and alternative medicine is increasing worldwide (8). Complementary and alternative therapies may have been used in about 64% of patients with ADHD (9). Dietary modifications and natural products (eg, herbs and vitamins) were the most reported modalities (8). Persian medicine (PM), as one of the complementary medicine methods, offers several treatment approaches for preventing and treating diseases at various stages of life, including childhood. Studies indicate the effectiveness of PM treatments, especially in children who are resistant to stimulant treatments (10). In PM, treatment includes 3 parts: lifestyle modification (including nutrition, sleep, exercise, etc), drug therapy, and manual therapies (cupping, leech therapy, and massage, etc) (11). Nutrition plays a vital role in the prevention and treatment of diseases, including ADHD (10). In Persian medicine, both sweet almonds and figs are brain tonics and are helpful for neurological diseases (12). Almonds and figs both have high antioxidant content, such as polyphenols, which play a key role in protecting nerve cells from damage caused by oxidative stress (13, 14) and they have neuroprotective effects.

In a clinical trial, the effectiveness and safety of sweet almonds were evaluated in children with ADHD. Based on the results of this study, sweet almonds may be an effective treatment for children with attention deficit disorder (15). Ficus carica has several therapeutic effects, such as antioxidant, laxative, anti-neurodegenerative, and neuroprotective (16).

This study aimed to investigate the effect of 2 types of treatments used in the PM ("sweet almond syrup" and "almond plus fig syrup") in controlling and improving the symptoms of children (6 to 14-year-olds) suffering from hyperactivity disorder and attention deficit disorder.

Methods

Study Design

This double-masked clinical study was conducted from April 2022 to December 2022. In this study, children aged 6 to 14 years with ADHD, who were diagnosed with this disorder by a psychiatrist based on the DSM-5 criteria, were referred to the pediatric psychiatry subspecialty clinics (Imam Khomeini Hospital, Children's Medical Center Hospital, Ziaian Hospital). This study was registered in the Iranian Registry of Clinical Trials (registration number: IRCT20220406054433N1). The Ethics Committee of the Research Center of Iran University of Medical Sciences also approved this study. (IR.IUMS.REC.1400.1264).

Inclusion Criteria

Patients with ADHD (6 to 14 years old) were included in this study after confirming the diagnosis by a psychiatrist and obtaining informed consent from their parents or guardians.

Exclusion Criteria

Children with significant chronic diseases—such as cardiovascular and gastrointestinal disorders, epilepsy, organic brain problems, schizophrenia, and intellectual disability with an intelligence quotient (IQ) below 70—were excluded from the study. Additional exclusion criteria included symptoms of allergy to sweet almonds or figs, intolerance to sweet almond syrup or the almond–fig combination, lack of parental or patient consent to continue treatment, development of another mental illness during the study requiring pharmacologic therapy, and the need to receive psychotherapy.

Randomization and Masking

In this study, blocks of 3 and 6 were used for randomization, and the size of the blocks was unknown to the individuals implementing the plan. Only the statistician was aware of this information. The person responsible for opening the envelopes grouped the participants and assigned the medicine accordingly. RAND software was used for randomization. The medicines were in containers of the same shape and color, and the patient and parents could not notice the difference in appearance; the treatment staff and psychologist were not aware of it, and concealment was observed.

Interventions

Patients were randomly divided into 3 groups (A, B, and C). All groups received the standard drug methylphenidate (Ritalin; Novartis) with a dose of 1 mg/kg/day. In addition to the standard drug, group A received Tinlose Syrup (the combination of almond and fig), group B received sweet almond syrup, and group C received an ineffective syrup as a placebo. The dose of syrup in all three groups was 5 cc, administered 3 times a day, for 12 weeks.

Outcome Measurement

In this study, the primary outcome was the severity of ADHD, assessed using the short and revised version of the Connors Rating Scale (CPRS-R-S) and the Parent ADHD

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Rating Scale questionnaire score.

The short and revised version of the Connors Rating Scale (CPRS-R-S), which was completed by one parent, consisted of four subscales: Oppositional, cognitive/attention problems, hyperactivity, and a General ADHD Index. This scale was investigated at the beginning of the study (before the intervention) and 12 weeks after the start of the drug. Connors et al reported the reliability of this scale as 0.90 (17, 18). The validity of the Persian questionnaire has been reported by the Institute of Cognitive Sciences as 0.85 (19) and was reliable (20).

Severity of ADHD based on the Parent ADHD rating scale questionnaire score at the beginning of the study (before the intervention), 4, 8, and 12 weeks after starting the drug was investigated. The Parent ADHD Rating Scale is a valuable tool for assessing ADHD symptoms in children and has been tested for reliability and validity (21).

The ADHD rating scale is a precise instrument consisting of 18 items that reasonably determine the type and severity of attention deficit/hyperactivity disorder. This scale has been widely used in Iran in school-age children, and its validity and reliability have been confirmed (22-24). The assessment of the severity of the disease is based on the 18-question form of the ADHD rating scale, which is completed by asking parents. The options for each question contain 4 options as follows: 0 = never or rarely, 1 = sometimes, 2 = often, 3 = very often.

Secondary Outcomes were the evaluation of drug side effects. To assess any potential adverse events, the Common Terminology criteria for adverse events (CTCAE, version 4.03, 2010) were used every 2 weeks after the start of treatment.

Statistical Analysis

SPSS Version 22 software was used to perform statistical analyses. Descriptive statistics analysis was used for qualitative findings. Covariance analysis was used to analyze the data. The assumptions of analysis of covariance (ANCOVA), such as normality and equality of variance, were checked. Wherever the assumptions were not satisfied, the nonparametric version of ANCOVA, which is quad ANCOVA, was used to compare the outcomes between groups. Tukey's post hoc analysis was also used to compare the two groups. Statistical significance level was set at 0.05.

Sample Size

In this study, the sample size was estimated based on the comparison of the average score of the primary outcome. The scores obtained from the ADHD rating scale questionnaire in the 3 studied groups, with a power of 80% and a probability of type 1 error of 5% for the aver-

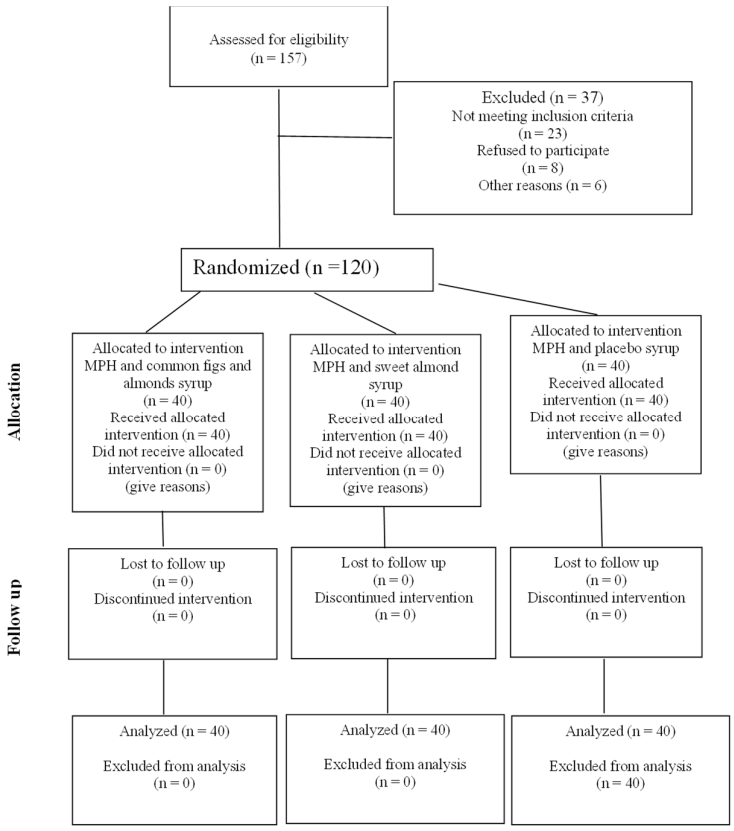

Figure 1. Consort diagram

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Table 1. Demographic characteristics of the participants

Variable		group A (N=40)	group B (N=40)	group C (N=40)	P value
Age Mean ± SD		9.40±2.30	9.82±2.65	10.67±2.67	0.079
Sex N/(%)	boy	33(82.5%)	32(80%)	31(77.5%)	0.578
	girl	7(17.5%)	8(20%)	9 (22.5%)	
BMI		18,67±1,83	18,56±1,73	18,49±2,15	0.679

Mean ± SD: A (common figs and almonds syrup), B (sweet almond syrup) and C (placebo)

age effect size (d = 0.7), were analyzed. There were 40 patients in each group, totaling 120 participants.

Results

At the beginning of the study, 157 patients were investigated. However, 37 (23 due to lack of entry criteria, 8 due to unwillingness to cooperate, and 6 due to other reasons) were excluded from the study. A total of 120 patients who met the inclusion criteria were randomly divided into 3 groups (n = 40 patients in each group) (Figure 1). There was no significant difference in demographic information, including age, sex, and body mass index (Table 1).

Outcomes

The Connors Rating Scale-Revised (CPRS-R-S)

According to the study results, there was a significant difference in the Oppositional subscale between the 3 groups at week 12 (P = 0.027) (Table 2, Figure 2). There was a significant difference in the subscale Oppositional between groups A and C (P = 0.045). However, this difference was not significant between groups A and B (P = 0.058), and B and C (P = 0.994) (Table 2).

In addition, the cognitive problems/inattention significantly improved in groups A and B more than the placebo in the 12 weeks (P = 0.009) (Table 2, Figure 3). There was a significant difference in subscale cognitive problems/inattention between groups A and C (P = 0.046), and a significant difference between groups B and C (P = 0.011). However, there was no significant difference between groups A and B (P = 0.850) (Table 2).

There was no significant difference in hyperactivity between the 3 groups in any of the visits (P =0.75) (Table 2, Figure 4).

There was no significant difference in the general ADHD index between the 3 groups in all visits (P = 0.660) (Table 2, Figure 5).

The Parent ADHD Rating Scale

Analytical comparison of the parents' ADHD Rating Scale scores in the inattention category (Figure 6) showed that the amount of reduction of inattention in group A in the eighth week 8 week in group A was higher than in the

Table 2. Comparison of ADHD symptoms based on the Connors Parent Questionnaire in children with attention deficit hyperactivity disorder

Variable		N	Mean	Std. Deviation	P-value between the 3 groups	Post hoc analysis between two groups (Tukey) Compare two groups		Mean Difference	Std. Error	p value
week1 subscale Oppositional	A	40	9.67	3.56	0.314	A	B	-.62	.96	.795
	B	40	10.30	4.43		B	C	1.47	.96	.284
	C	40	8.82	4.87		C	A	-.85	.96	.655
week1 subscale cognitive problems/inattention	A	40	10.87	5.06	0.002*	A	B	-.70	1.04	.781
	B	40	11.57	3.52		B	C	3.52	1.04	.003*
	C	40	8.05	5.22		C	A	-2.82	1.04	.021*
week1 subscale hyperactivity	A	40	8.55	4.85	0.546	A	B	-.75	1.16	.795
	B	40	9.30	5.42		B	C	1.27	1.16	.518
	C	40	8.02	5.28		C	A	-.52	1.16	.894
week1 subscale general ADHD index	A	40	20.22	8.73	0.140	A	B	-.87	1.76	.874
	B	40	21.10	6.78		B	C	3.40	1.76	.136
	C	40	17.70	8.04		C	A	-2.52	1.76	.329
week12 subscale Oppositional	A	40	8.17	3.09	0.027*	A	B	1.60	.69	.058
	B	40	6.57	3.24		B	C	.07	.69	.994
	C	40	6.50	2.94		C	A	-1.67	.69	.045*
week12 subscale cognitive problems/inattention	A	40	6.55	2.63	0.009*	A	B	.35	.64	.850
	B	40	6.20	2.28		B	C	-1.90	.64	.011
	C	40	8.10	3.56		C	A	1.55	.64	.046*
week12 subscale hyperactivity	A	40	5.55	2.80	0.750	A	B	.47	.62	.728
	B	40	5.07	2.62		B	C	-.22	.62	.931
	C	40	5.30	2.94		C	A	-.25	.62	.916
week12 subscale general ADHD index	A	40	13.70	4.18	0.660	A	B	.50	1.01	.875
	B	40	13.20	4.22		B	C	-.92	1.01	.634
	C	40	14.12	5.13		C	A	.42	1.01	.908

*P≤0.05 was significant

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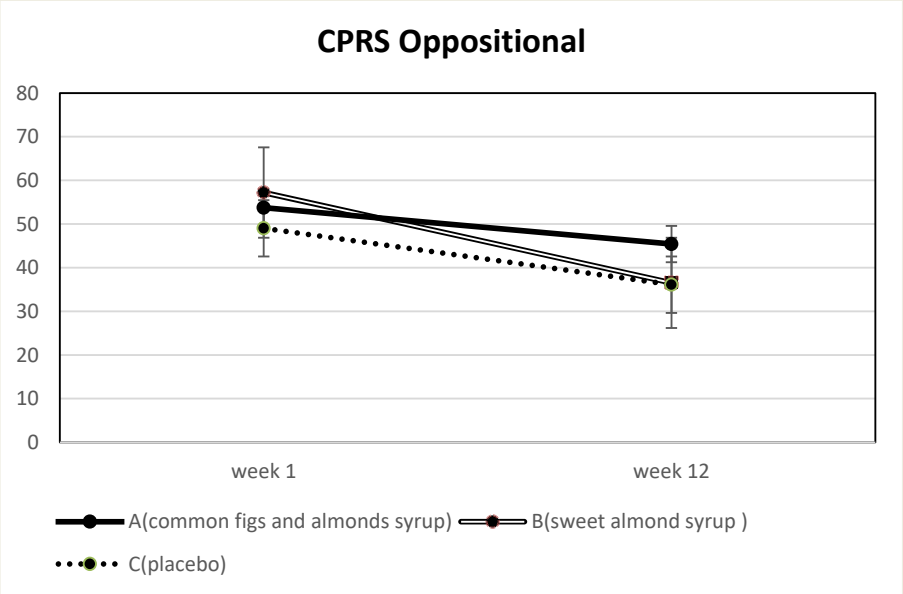

Figure 2. Comparison of Oppositional based on Connors parents' questionnaire in children with attention deficit hyperactivity disorder in three groups: A (common figs and almonds syrup), B (sweet almond syrup) and C (placebo) P=0.027

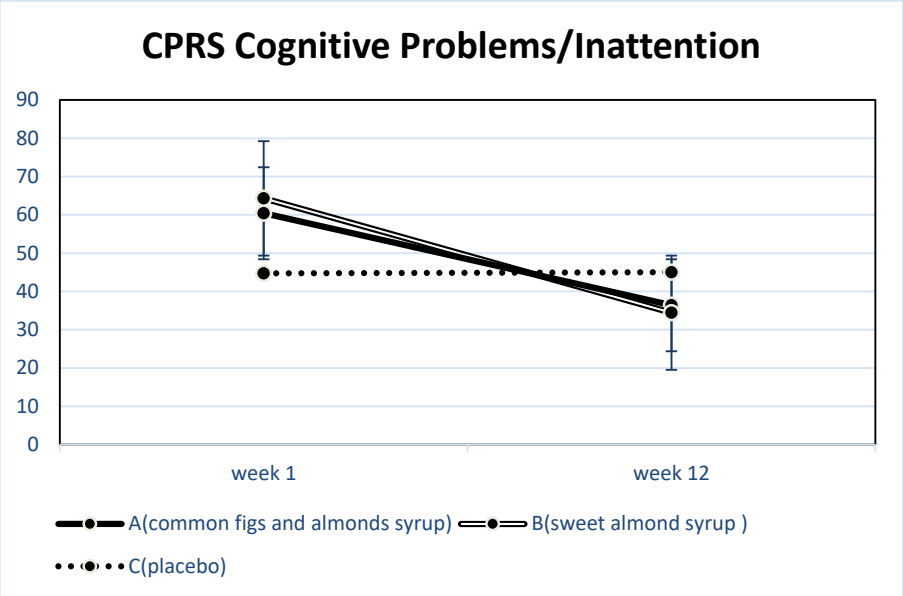

Figure 3. Comparison of cognitive problems/inattention based on Connors parent questionnaire in children with attention deficit hyperactivity disorder in three groups: A (common figs and almonds syrup), B (sweet almond syrup) and C (placebo) P=0.009

other 2 groups. In the twelfth week, the mean reduction in group B was significantly greater than in group C (P = 0.018). This reduction was similar in groups A and B.

Analytical comparison of the parents' ADHD Rating Scale scores in the hyperactivity category (Figure 7) showed that the reduction of hyperactivity in weeks 4 to 8 in group A was more than in group B. In the 12th week, there was no significant difference in the three groups (P = 0.179).

Improving the ADHD Rating Scale in weeks 4 to 8 in group A was more than in group B (P = 0.039). In the 12th week, there was no significant difference in the three groups (P = 0.039) (Figure 8).

Safety and Tolerability

No serious side effects were observed during the study. In group A (patients receiving combined fig syrup and sweet almond), the most commonly reported side effects

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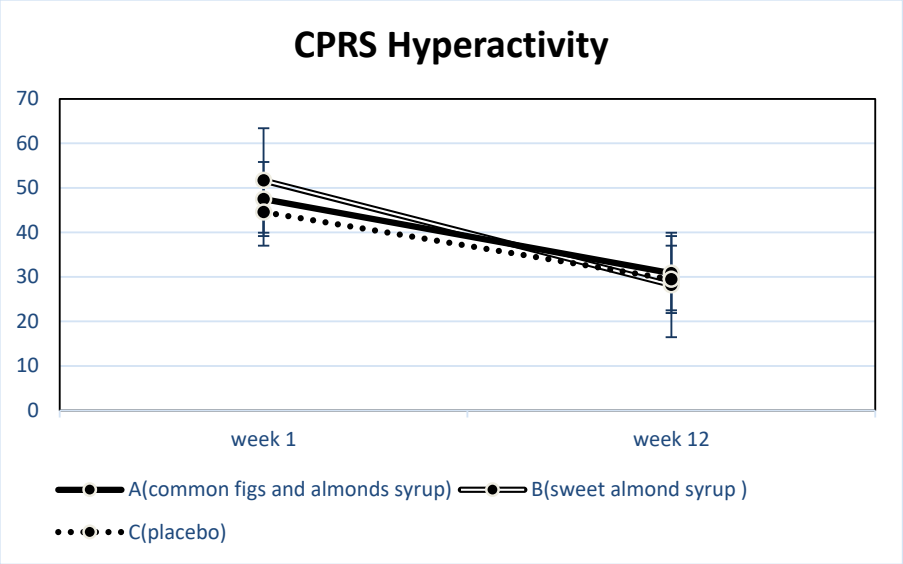

Figure 4. Comparison of hyperactivity based on Connors parent questionnaire in children with attention deficit hyperactivity disorder in three groups: A (common figs and almonds syrup), B (sweet almond syrup) and C (placebo) P=0.75

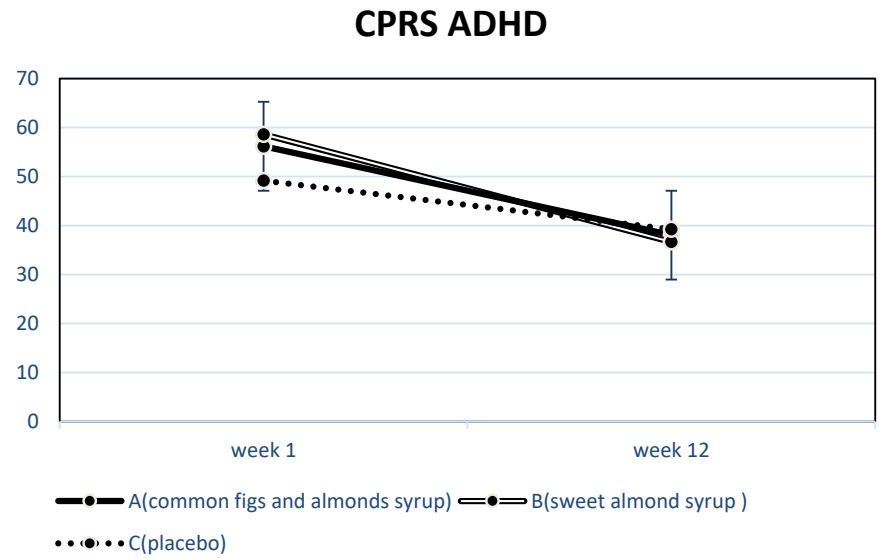

Figure 5. Comparison of general ADHD index based on Connors parent questionnaire in children with attention deficit hyperactivity disorder in three groups: A (common figs and almonds syrup), B (sweet almond syrup) and C (placebo) P=0.660

are increased appetite, irritability, and restlessness. The most common side effects in group B (patients receiving syrup sweet almond) included increased appetite, irritability, and tiredness, and the most common side effects in group C (patients receiving syrup Placebo) included restlessness, irritability, and fatigue (Table 3).

Discussion

The results of the present study showed that the combined fig and sweet almond syrup was more effective in improving inattention at week 8 of the intervention compared with either sweet almond syrup alone or placebo. Also, this study showed that the combined syrup of figs and sweet almonds significantly improved cognitive/attention problems compared to a placebo at week 12, and there was no difference in the efficacy of these 2 drugs together. Oppositional improvement at week 12 was greater in the fig-almond combination group than in the sweet almond and placebo groups. Nevertheless, the effect of fig and sweet almond combined syrup on hyperactivity

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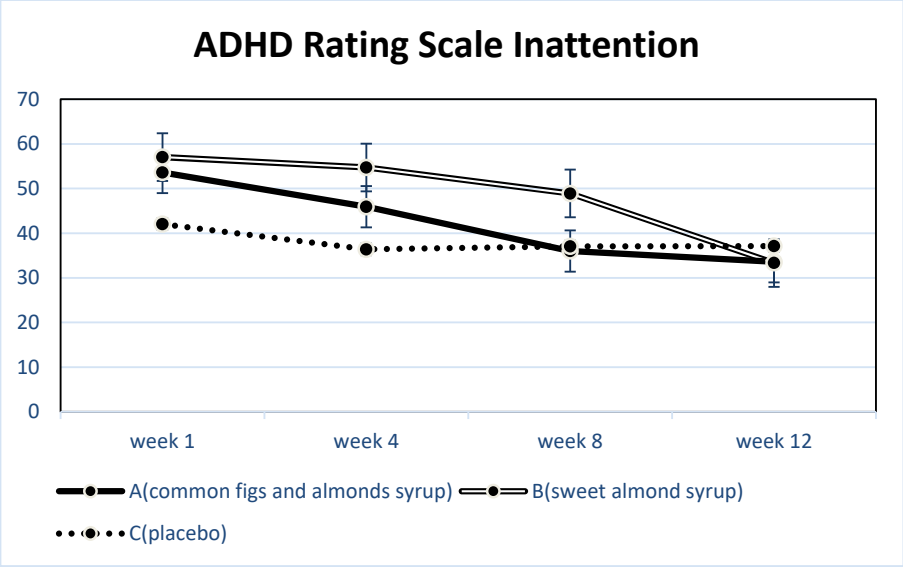

Figure 6. Comparison of inattention based on ADHD Rating Scale in children with ADHD (attention-deficit/hyperactivity disorder) in three groups: A (common figs and almonds syrup), B (sweet almond syrup) and C (placebo) p=0.018

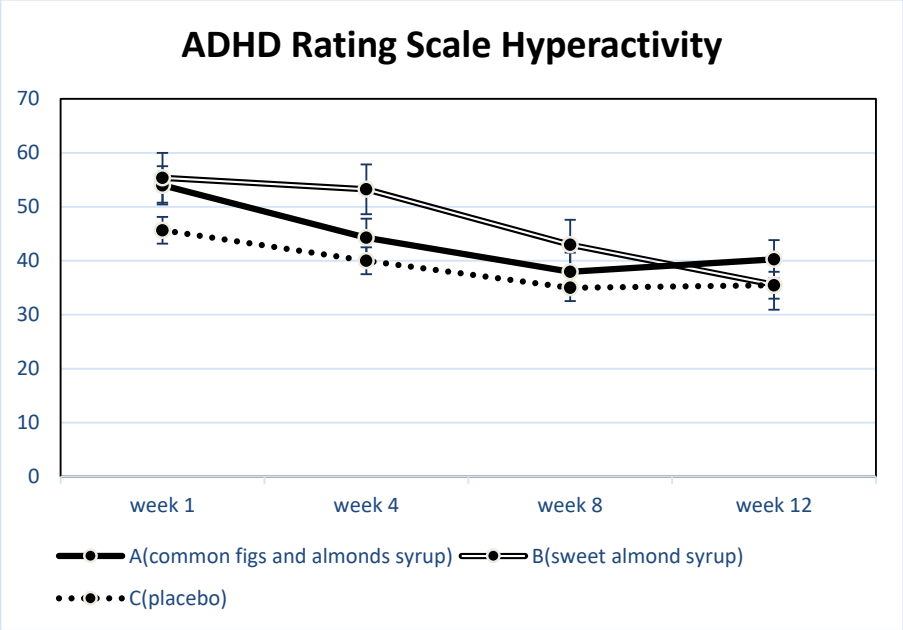

Figure 7. Comparison of hyperactivity based on ADHD Rating Scale in children with attention deficit hyperactivity disorder in three groups: A (common figs and almonds syrup), B (sweet almond syrup) and C (placebo) p=0.179

was not significantly different from placebo. Other animal or clinical studies on the effectiveness of figs on ADHD were not found. However, several studies have been conducted on the efficacy of figs on cognitive and memory disorders.

In an animal study on rats, it was found that the mixture of F. carica and olive oil improved neurological functions in rats and increased memory function by inhibiting oxidative activity and reducing acetylcholinesterase levels (25). In another animal study, mice were fed a fig-supplemented diet for 15 months. Their results clearly showed that nutritional supplements with figs significantly improve learning and memory deficits, motor coordination, and reduce anxiety in a mouse model for Alzheimer's disease. This study showed that a diet rich in figs has neuroprotective effects on cognitive and behavioral deficits (26). Studies show that F. carica has antioxidant, anti-inflammatory, and neurotrophic properties (27).

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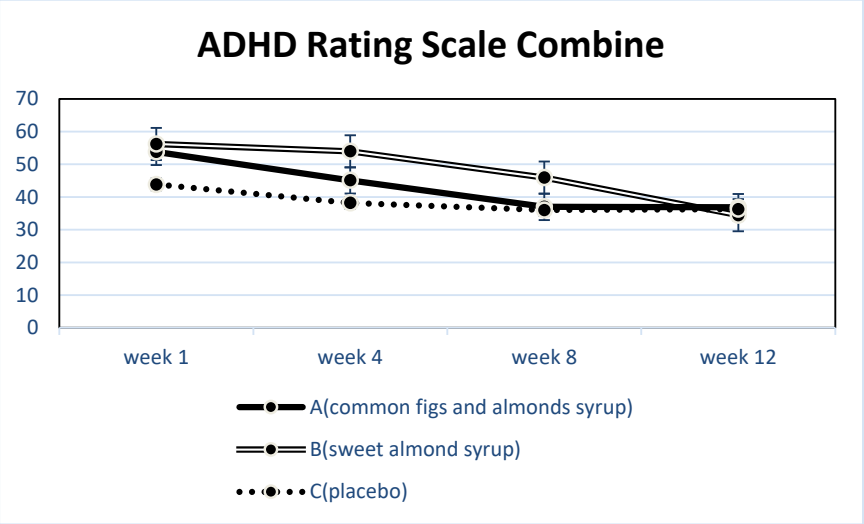

Figure 8. Comparison of combine based on ADHD Rating Scale in children with ADHD (attention-deficit/hyperactivity disorder) in three groups: A (common figs and almonds syrup), B (sweet almond syrup) and C (placebo) *P*= 0.039.

Table 3. Frequency of the side effects in the three study groups: A (common figs and almonds syrup), B (sweet almond syrup) and C (placebo)

Complication	A (n=40)	B (n=40)	C (n=40)	*P*- value
loss of appetite	2 (5%)	4 (10%)	22 (55%)	<0.001
Increased appetite	38 (95%)	39 (97.5%)	5 (12.5%)	<0.001
Decreased sleep duration	15 (37.5%)	14 (35%)	18 (45%)	0.635
Increased sleep duration	25 (62.5%)	21 (52.5.5%)	26 (65%)	0.482
Sleeping late	22 (55%)	25 (62.5%)	18 (45%)	0.289
Interrupted and irregular sleep	28 (70%)	30 (75%)	22 (55%)	0.142
Drowsiness during the day	6 (15%)	7 (17.5%)	3 (7.5%)	0.392
Morning sleepiness	17 (42.5%)	26 (65%)	15 (37.5%)	0.032
Nightmares	12 (30%)	12 (30%)	4 (10%)	0.051
abdominal pain	11 (27.5%)	8 (20%)	4 (10%)	0.137
Nausea	7 (17.5%)	4 (10%)	2 (5%)	0.194
Vomiting	2 (5%)	0 (0%)	1 (2.5%)	0.359
Constipation	10 (25%)	11 (27.5%)	10 (25%)	0.957
Diarrhea	3 (7.5%)	0 (0%)	1 (2.5%)	0.164
Trouble swallowing	2 (5%)	1 (2.5%)	0 (0%)	0.359
sore throat	4 (10%)	5 (12.5%)	4 (10%)	0.917
dry mouth	3 (7.5%)	5 (12.5%)	12 (30%)	0.018
Drooling	17 (42.5%)	15 (37.5%)	5 (12.5%)	0.008
Headache	6 (15%)	4 (10%)	2 (5%)	0.329
Dizziness	4 (10%)	5 (12.5%)	1 (2.5%)	0.242
Restlessness	33 (82.5%)	30 (75%)	36 (90%)	0.210
Irritability	35 (87.5%)	34 (85%)	31 (77.5%)	0.458
Sadness or crying	13 (32.5%)	15 (37.5%)	7 (17.5%)	0.123
Nail biting	15 (37.5%)	15 (37.5%)	11 (27.5%)	0.553
Quiet and self-absorbed	14 (35%)	15 (37.5%)	10 (25%)	0.45
Tiredness	27 (67.5%)	34 (85%)	28 (70%)	0.154
Slow movements	13 (32.5%)	10 (25%)	2 (5%)	0.007
Muscle stiffness	3 (7.5%)	3 (7.5%)	2 (5%)	0.875
Tic	5 (12.5%)	5 (12.5%)	0 (0%)	0.065
Tremor	3 (7.5%)	0 (0%)	0 (0%)	0.046
Blurred vision	5 (12.5%)	3 (7.5%)	0 (0%)	0.079
Palpitations	9 (22.5%)	5 (12.5%)	0 (0%)	0.007
Tingling hands or feet	10 (25%)	7 (17.5%)	7 (17.5%)	0.626
Feeling unbalanced	4 (10%)	5 (12.5%)	6 (15%)	0.796
Nocturnal enuresis	6 (15%)	4 (10%)	5 (12.5%)	0.796
delay Urinary (Urinary retention)	30 (75%)	31 (77.5%)	20 (50%)	0.015
Bloody urine	0 (0%)	1 (2.5%)	0 (0%)	0.365
Itching	4 (10%)	0 (0%)	2 (5%)	0.122
Skin rash and pimples	0 (0%)	0 (0%)	1 (2.5%)	0.365

In a clinical trial, the effectiveness of sweet almonds was evaluated in 50 children aged 6 to 14 years with ADHD. Participants were randomly divided into 2 groups (receive either methylphenidate or sweet almond syrup). The results were evaluated using the ADHD scoring scale of parents and teachers every 2 weeks for 8 weeks. Their results showed that the 2 treatment methods had a similar effect in reducing the symptoms of children with ADHD,

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with no significant difference between the 2 groups. In this study, the effectiveness of sweet almond syrup on hyperactivity and inattention was similar to that of methylphenidate, and there was no significant difference between them (15). The duration of this study was 8 weeks, and our study lasted 12 weeks, which was longer than their study. In this study, the sweet almond group received only this syrup; however, in our study, all groups received standard treatment along with herbal syrups or a placebo.

In another clinical study, Salehi et al studied the effect of Ginkgo biloba on ADHD treatment in 50 children for 6 weeks. Patients were randomly divided into 2 groups: those receiving Ginkgo biloba tablets (Group 1) and those receiving methylphenidate tablets (Group 2). The results of this study showed that ginkgo administration was less effective than methylphenidate in treating ADHD. There was no significant difference in the frequency of side effects between the ginkgo and methylphenidate groups, except for decreased appetite, headache, and insomnia, which were more frequently observed in the methylphenidate group (23).

The duration of this study was 6 weeks, while that of our study was 12 weeks. In this study, the ginkgo group received only this herbal medicine, whereas in our study, all groups received the standard drug (methylphenidate) and, in addition, either traditional medicine (fig and sweet almond oil or placebo syrup). There was no significant difference in the frequency of side effects between the ginkgo and methylphenidate groups, except for decreased appetite, headache, and insomnia, which were more frequently observed in the methylphenidate group. In our study, the frequency of side effects did not differ significantly among the three groups, and decreased appetite and dry mouth were more frequent in the methylphenidate group. Our study showed that the combined syrup of fig and sweet almond, as well as sweet almond alone, significantly improved Oppositional and cognitive/attention problems compared to the placebo at week 12. This means that taking these syrups in conjunction with the standard medication (methylphenidate) has a synergistic effect in treating this disease.

In an animal study, female mice were fed a special diet containing 5% (w/w) almonds during the mating period (2 days) and the gestation period (21 consecutive days). The results of this study showed that eating almonds before birth improves memory, reduces anxiety-like behaviors, and increases adaptation to stress in adult offspring (28).

An essential advantage of this study is the safety and fewer side effects of fig + sweet almond syrup. Another essential benefit of this natural treatment is the lower abuse of fig + sweet almond syrup compared to methylphenidate.

Conclusion

This study indicated that Tinlose syrup (figs + sweet almonds) could be a safe and effective alternative and complementary medicine in the adjuvant medication of ADHD in children. Tinulose syrup may be recommended for children with ADHD as an adjunct to stimulant medications, particularly to help reduce their adverse effects.

Authors' Contributions

HMK contributed to the study design, drafting of the initial manuscript, and revision and approval of the final version.

ME participated in the study design, data collection, and revision and approval of the final version.

MSY contributed to the study design, data analysis, and interpretation, and revised and approved the final manuscript.

MK and GK participated in the study design.

JA contributed to drafting the initial manuscript.

GRD assisted in data collection.

AM contributed to the study design, data collection, drafting of the initial manuscript, and revision and approval of the final version.

All authors read and approved the final manuscript.

Ethical Considerations

This clinical trial was conducted in accordance with the ethical standards of the Declaration of Helsinki and was approved by the Ethics Committee of Iran University of Medical Sciences (Ethics Code IR.IUMS.REC.1400.1264. The study protocol was also registered in the Iranian Registry of Clinical Trials (IRCT20220406054433N1). Written informed consent was obtained from the parents or legal guardians of all participants, and verbal assent was obtained from the children whenever applicable. Participation was entirely voluntary, and participants were free to withdraw at any stage without any consequences. All collected data were kept confidential and used solely for research purposes.

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Conflict of Interests

The authors declare that they have no competing interests.

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