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Effects of High-Protein Diet on Weight and Height Growth in Children with Attention Deficit Hyperactivity Disorder Receiving Ritalin: a Randomized Clinical Trial

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Abstract

Background: Children with Attention-Deficit/Hyperactivity Disorder (ADHD) who take Ritalin may be faced with appetite reduction and weight loss. Herein, we aimed to evaluate the effects of a high-protein diet on weight and height growth in children with ADHD receiving Ritalin.
Methods: In this randomized controlled trial, performed during 2016-2018 in Tehran, 50 children with ADHD treated with Ritalin were randomly assigned to the high-protein diet (HPD) group (35% of the total calories intake from protein) or the control group receiving a standard diet (STD) (15% of the total calories from protein). The height and weight were measured in the standard mode and three-day food record was completed at baseline. The measurements were repeated on a monthly basis for 5 months. We used independent sample t-test to analyze the data. The study protocol was registered in the Iranian Registry of Clinical Trials with the code of IRCT2014062116465N4.
Results: A total of 40 children and adolescents (19 in HPD and 21 in STD) completed the study. Baseline characteristics between the trial arms were equal. After 5 months, the protein intake of HPD group was significantly higher based on a seven-day food record. In girls' subgroup, after 5 months, the mean difference concerning height, weight, and BMI change in HPD group compared to the control group were respectively +0.5 cm (P =0.41), -2.5 kg (P=0.04), and -1.6 kg/m2 (P=0.01) while in boys' subgroup, they were +0.4 cm (P=0.59),+0.3 kg (P =0.37), and+0.02 kg/m2 (P=0.51).
Conclusion: Girls responded differently to the HPD. The BMI in the girls decreased significantly after 5 months of HPD consumption as a result of weight loss. This effect was not observed in the boys. This may be due to different patterns of growth and puberty in the two genders.

*Keywords***:** ADHD, Children, Diet, Growth, Protein

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1. Introduction

Attention-Deficit/Hyperactivity Disorder (ADHD) in children features a deep influence on child's behavior and growth progression (1). Impulsive behaviors in children with ADHD have profound influence on eating behavior and food choice. Ptacek and colleagues revealed a disturbed eating pattern in ADHD children. They consumed more sweetened beverages and junk foods, and lower nutritional quality foods (2). Azadbakht and Esmailzadeh revealed a significant correlation between ADHD and consumption of fast foods and sweets in children (3). Abbasi and co-workers revealed inverse association between healthy eating pattern and ADHD (4).

The first line medication in treating ADHD children is Methylphenidate (Ritalin). Methylphenidate inhibits dopamine receptors and cause an increase in dopaminergic system and decreasing appetite. The ADHD children on methylphenidate may lose their body weight and developmental growth especially in the first 3 to 6 month of intake (5). Following the intake of Ritalin, these children may lose their appetite, which leads to a decrease in the intake of foods and subsequently reduces the growth and body weight (6, 7). Nutritional status and developmental trajectory of the children and adolescents with ADHD may be compromised by the behavioral defects of the disorder and also by the Ritalin medication (8). Schneider and colleagues in a longitudinal study revealed decreasing body weight and height growth following administration of stimulant drugs in children with ADHD (9). Kim and co-workers in a study of the effects of methylphenidate on height and weight growth in children with ADHD revealed that weight and height decreased significantly compared to standard growth chart in patient receiving methylphenidate (10).

Decreased height and weight gain in children can be the sign of reduced appetite and a low-protein diet intake (11). The amounts of protein requirement vary depending on height, age, and body size and in boys; it is higher than that in girls. On the other hand, during the growth period, the amount of protein intake increases. The most powerful association of the total protein in the diet and growth of girls and boys have been reported during the rapid growth period of puberty (12). Moreover, daily protein mixture has a direct correlation with the growth intensity and higher energy derived from proteins other than grains, it is also associated with higher weight growth (13). Hoppe and colleagues showed that protein intake in infancy is strongly associated with body size (weight, height) at nine months. Furthermore, height and weight at the age of 10 is correlated with the protein received at age of nine months (14).

Investigators have shown that regular milk drinking in children is associated with height in adulthood. Milk is a drink rich in a high quality protein, it contains protein, calcium, and other compounds, which are required for bone growth (15). Decreased protein intake in childhood causes a reduction in the weight-to-height ratio (16). Kabir and colleagues reported that children in recovery period who consumed a high-protein diet in a six-month period increased catch-up growth and gained more height (17).

Gately and co-workers in a trial of a high-protein diet (22.5% of calorie from protein) on body weight and appetite of overweight children revealed no difference between the intervention group and the control group (15% of calorie from protein) (18). Duckworth and colleagues in a clinical trial of a restricted calorie high-protein diet on weight and appetite of obese children, failed to prove the effects of the high-protein diet on decreasing body weight and appetite. They defined the high-protein diet as 25% of total calorie intake from protein and standard protein as 15% of total calorie from protein (19). However our aim and target group (ADHD children) is different from their study population. In this research, we want to target decreased growth in ADHD children by a high-protein diet. By the literature review performed, discrepancy on the effects of high-protein diet on body weight and height in different populations of children (healthy or patient) is obvious. Furthermore, lack of knowledge on effects of high-protein diet on ADHD children is apparent.

Even though we know that weight decreases in children with ADHD especially in the first 6 months of taking Ritalin, and we postulated the influence of the high-protein diet in growth, no investigations has been performed to date on the effects of a high-protein diet in children with ADHD. Hence, we designed a randomized clinical trial and aimed to assess the effects of high-protein diet on growth in children with ADHD receiving Ritalin.

2. Methods

Study design

This randomized clinical trial was an open label study conducted on 2016-2018 and the participants were selected from a child and adolescent psychiatric clinic located in Tehran, Iran. In order to decrease the selection bias, the sampling method we used was the simple random allocation with the Excel framework and RAND function. Furthermore, we performed allocation concealment technique; accordingly, up to the allocation moment, the participants were naïve to the intervention groups. The patients were randomly distributed to the trial arms (group A or group B) based on the order they arrived. From the investigator team, only the dietitian knew that which group is high-protein diet or the standard diet. The groups were blinded to the person responsible for random allocation (child and adolescents psychiatrist) and the statistical analyst. The study protocol was registered in the Iranian Registry of Clinical Trials with the code of IRCT2014062116465N4.

Sample size

We determined the sample size based on expected mean difference of 2 kg ($\mu 1-\mu 2 = 2$) (according to clinical experience) (20), $\alpha = 0.05$ and power of 80%. Furthermore, we selected the standard deviation of weight in children and adolescents according to previous studies (21).

Procedure

Children aged 7 to 12 years, who were diagnosed with ADHD by a child and adolescent psychiatrist according to the DSM-5 criteria, were eligible to participate. In this trial, 50 children with ADHD were referred to a child and adolescent psychiatric clinic, who received the first line selective Ritalin and were randomly assigned to two groups of high-protein diet or the standard protein group as the control group.

During the first visit, after obtaining the written informed consent from their parents and oral assent from children, height (cm) and weight (kg) of children were measured in standard mode by a trained dietitian. They received a three-day food record with instructions and exchange list to be completed in home with the help of parents and the child themselves. Subsequently, they were randomly divided into two groups.

The children in the high-protein group received a diet with 35% total calorie intake from proteins. The children in the control group received the standard diet with 15% total calorie intake from proteins. An expert dietitian prescribed diets according to the children's age, height, and weight. Both groups received Ritalin based on a child and adolescent psychiatrist›s diagnosis. Throughout the process of the study, the measurements were repeated on a monthly basis and the children dietary intake and adherence were monitored with seven-day food records.

Inclusion and exclusion criteria

The inclusion criteria were children and adolescents between 7 to 12 years old, newly diagnosed with ADHD based on DSM-5 criteria. The exclusion criteria were not consenting to participate and poor adherence to the study protocol (those with at least 20% violation of the diet's protein were excluded).

Data collection

Dietary intake of the participants was assessed via the three-day food record at baseline and seven-day food records during one-month intervals. A qualified dietitian randomly selected the week's days for recording the dietary intake and offered the exchange list and instructed the parents to involve the child and record every exchange of foods the child eats. The literature reported that reliability of food records in estimating dietary intake of subjects, particularly in children and sex, did not influence the reliability of nutrients estimation (22).

Study tools

Scale: We measured the accurate weight of children with an accurate scale (Seca, German) while the subjects were wearing the least possible costume. The reliability of scale was assessed in a pilot study on 10 participants with a high correlation between three subsequent measurements (r=0.92; P= 0.01).

Stadiometer: We measured the participants accurate height utilizing Seca wall height gauge (Seca, German) while the subjects were standing with their back to the wall and without shoes. The reliability of the scale was assessed in a pilot study on 10 participants with a high correlation between three subsequent measurements (r=1.0; P=0.01).

Three-day food record

The three-day food record is a dietary assessment tool aiming to gather accurate data of the current dietary intake of micro and macronutrients. The investigator randomly selected one holiday and some working days and wanted the parents to write down every food or beverage their child eats and drinks each day as well as brand names and cooking method of foods. This method is more accurate than food recall and food frequency and its reliability and validity is approved with an acceptable correlation with other dietary intake assessment techniques (Pearson's correlation coefficient between the three-day food record and nine-day food record was 0.56) (23).

Statistical analyses

We primarily assessed the normality of the variables with Kolmogorov-Smirnov and Shapiro-Wilk tests and the normality of variables was achieved. Afterwards, independent sample t-test was performed to compare the baseline variables between the groups and to compare the mean changes between the groups during the study period. We performed subgroup-analyses to assess and control the confounding effect of gender in growth. In each measurement interval, we reported the mean change from the baseline of body weight, height, and BMI as well as mean differences between the groups and their 95% confidence intervals, separately by gender subgroups. We analyzed the data employing the STATA version 11.

3. Results

A total of 40 children and adolescents (19 in high-protein diet and 21 in standard protein diet) completed the study (Figure 1). They aged between 6 to 14 years old (mean±SD=9.8 ±2.2). There were no significant differences between the groups regarding weight, height, BMI, gender distribution, and dietary calorie and protein intake and other demographic variables at baseline (Table 1). After 5 months, the calorie intake was equal between the groups (P=0.35), yet protein intake of high-protein diet group was significantly higher (P<0.001) based on the seven-day food record.

In the girls' subgroup, after 5 months, the BMI change from the baseline in high-protein diet group was -1.4 ± 1.1 kg/m2and in the control group, it was +0.2 ± 1.6 kg/m2; the mean difference (MD) between the groups was significant MD = -1.6 (P=0.01).

Height growth from the baseline to the 5th month in the high-protein diet group was 3.1 ± 1.8 cm and in the control group was 2.6 ± 0.9 cm. The mean difference between the groups was not statistically significant MD= 0.5 cm (p = 0.4). The weight change from the baseline until the 5th month in the high-protein diet group was -0.5 ± 2.4 kg and in the control group was +2.08 ± 3 kg. The mean difference between the groups

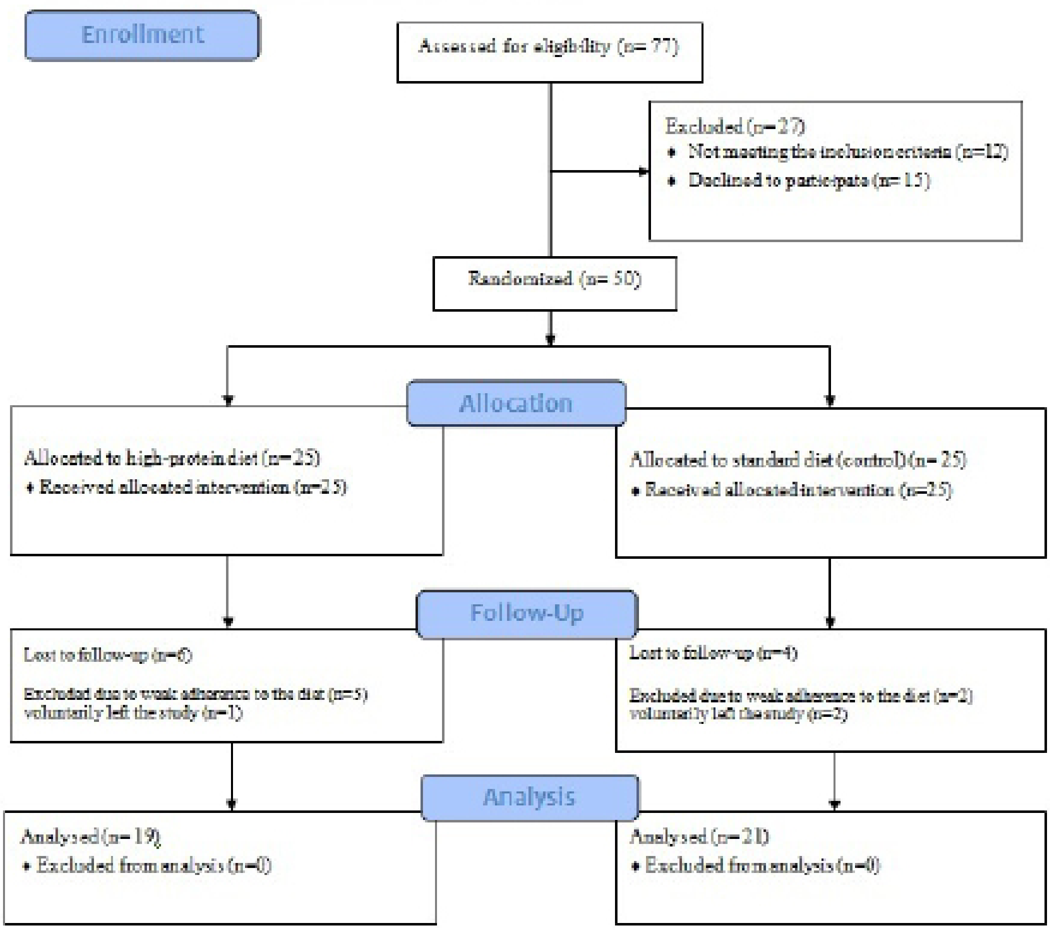

Figure 1: The figure shows the CONSORT flowchart of the study.

Table 1: Baseline variables in the standard protein diet compared with the high-protein diet

	Standard protein diet (N=21) (%) Mean±SD/N	**High-protein diet** (N=19) Mean±SD / N (%)	**P value**
Age	2.5 ± 9.6	2 ± 10	0.43
Weight	±23 39	±11 38.4	0.91
Height	20 ± 135.3	8.6 ± 136.1	0.87
BMI	±5.5 19.5	±4.1 20.3	0.62
Energy intake (kcal) before intervention	1661±409	1599±384	0.51
Energy intake (kcal) after intervention	1869.49±500	379±1735	0.35
Protein intake (g), before intervention	43±12	41±14	0.20
Protein intake (g) after intervention	40±14	119±24	0.001>
Sex			
Boys	(33%) 7	(47%) 9	0.28
Girls	(67%) 14	(53%) 10	
Family income			
Low-income	(9.5%) 2	(31.6%) 6	
Middle-income	(85.7%) 18	(63.2%) 12	0.21
High-income	(4.8%) 1	(5.3%) 1	
Father Education level			
Under graduate	(52.4%) 11	(68.4%) 13	
Graduated	(42.9%) 9	(21.1%) 4	0.31
Post Graduated	(4.8%) 1	(10.2%) 2	
Mather Education level			
Under graduate	(52.4%) 11	(52.6%) 10	
Graduated	(14.3%) 3	(36.8%) 7	0.11
Post Graduated	(33.3) 7	(10.5%) 2	

NS: not significant, S: significant

was statistically significant MD=-2.5 kg (P = 0.04) (Table 2). In the boys' subgroup, after 5 months, the BMI change from the baseline in the high-protein diet group was 0.24 ± 1 kg/m2 and in the control group was 0.006 ± 0.1 kg/m2. The mean difference between the groups was 0.023 kg/m2 (p = 0.51). The height change from the baseline to the5th month in the high-protein diet group was 3.5 ± 1.6 cm and in the control group was 3.07 ± 1.4 cm. The mean difference between the groups was 0.4 cm (P = 0.59). The weight change from the baseline until the 5th month in the high-protein diet group was 1.8 ± 0.7 kg and in the control group was 1.5 ± 0.8 kg. The mean difference between the groups was 0.3 kg (P = 0.37) (Table 3).

Table 2: Weight, height, and BMI changes in the girls with high-protein diet compared with those on standard protein diets within 5-month intervals

	Groups	N	Month 1			Month 2			Month 3			Month 4			Month 5		
			Change	SD	P	Change	SD	P	Change	SD	P	Change	SD	P	Change	SD	P
Weight (kg)	Standard Protein	14	0.30	0.7	0.08	0.53	1.7	0.09	1.06	2.0	*0.04	1.5	2.5	*0.04	2.08	3.0	*0.04
	High Protein	10	-0.45	1.3		-0.60	1.3		-0.5	1.5		-0.57	1.9		-0.51	2.4	
Height (cm)	Standard Protein	14	0.42	0.38	0.06	1.07	0.61	0.7	1.7	0.7	0.7	2.0	0.9	0.3	2.6	0.9	0.4
	High Protein	10	0.75	0.42		1.15	0.62		1.8	0.9		2.5	1.3		3.1	1.8	
BMI (kg/M^2)	Standard Protein	14	0.0	0.59	*0.007	-0.1	1.0	*0.03	-0.01	1.2	*0.01	0.16	1.4	*0.006	0.2	1.6	*0.01
	High Protein	10	-0.7	0.56		-0.9	0.6		-1.2	0.7		-1.4	0.6		-1.4	1.1	

Table 3: Weight, height, and BMI changes in the boys with high-protein diet compared with those on standard protein diets within 5-month intervals

	Groups	N	Month 1 Change	SD	p	Month 2 Change	SD	P	Month 3 Change	SD	P	Month 4 Change	SD	P	Month 5 Change	SD	P
Weight (kg)	Standard Protein	7	0.18	0.5	0.20	0.48	0.6	0.47	0.95	0.55	0.66	1.3	0.7	0.38	1.5	0.8	0.37
	High Protein	9	-0.11	0.3		0.72	0.6		0.83	0.55		1.6	0.5		1.8	0.7	
Height (cm)	Standard Protein	7	0.5	0.7	1.00	1.1	1.06	0.95	1.7	1.1	0.92	2.6	1.2	0.78	3.07	1.4	0.59
	High Protein	9	0.5	0.4		1.1	0.7		1.8	0.9		2.8	1.1		3.5	1.6	
BMI (kg/M^2)	Standard Protein	7	-0.002	0.2	0.21	-0.005	0.2	0.66	0.05	0.1	0.93	0.02	0.1	0.61	0.006	0.1	0.51
	High Protein	9	-0.14	0.1		0.06	0.4		0.07	0.6		0.1	0.6		0.24	1.0	

4. Discussion

In spite of similar height growth between genders, we observed different patterns of response to high-protein diet regarding body weight and BMI in boys and girls. In the girls' subgroup, after 5 months, the body weight and BMI decreased significantly compared to the control group. In our study, boys had higher BMI and weight gain than girls.

Torres and co-workers (24), in a prospective study on 238 Bangladeshi children aged 3 to 11 years, examined the association between protein intake and a one-year increase in height and weight in children aged 3 to 11 years. This study was conducted to prove the theory that the protein composition is associated with child growth rate and velocity. Anthropometric measurements were taken monthly. There were no significant relationships between stunted and wasted girls and boys. On the whole, children achieved 1.8 kg weight gain and 4.4 cm of height gain in a year (r =0.02, P=0.7). Height was related to age (B=-0.023 cm / y, P<0.001), yet the obtained weight didn't have a significant relationship with age. Compared to girls, boys gained more body weight (B for difference =265g / y, P≤0.03). Protein component of the diet included an average of (11.7 % ±1.7) of the total energy intake.

The energy derived from protein could have increased weight in children. In our study, different growth periods and higher protein intake was investigated, which justified different responses of boys and girls to high-protein diet.

Wait (25) investigated 480 girls and boys aged 1 to 20 in Chicago. The children and adolescents› intake of protein in well-nourished children was evaluated. This study showed that protein intake is different in girls and boys, proportional to age, gender, degree of growth, and body size. Protein intake in boys was upper than that in girls. Furthermore, the total protein intake increases during growth. The highest relationship between the total protein intake in diet and weight or height of girls and boys from infancy to adolescence is during rapid growth of puberty. We also observed different patterns between boys and girls growth in relation to high-protein diet. This observed difference may be due to different puberty ages in girls and boys.

Hoppe and colleagues (14) studied the relationship between protein intake at nine-months-old infants and body weight or height at the age of 10. In this randomized cohort study, 142 healthy infants with 37 to 42 weeks of age (between 0-12 months old) were studied in Denmark. At the age of 9 months, the dietary intake, and anthropometric indices were assessed. Subsequently, at the age of 10 years old, 105 children from that cohort group were randomly selected and assessed. There was a correlation between the received protein (g / day) with anthropometric indices (height and weight), but the received protein was not correlated with the adipose tissue percentage at the age of 10. Protein in babies is a growth stimulator, which can explain the relationship between protein intake and body size at the age of 10. In this study, the median energy intake was 738 kcal/day, which was equal to 83.4 kcal per kilogram of the body weight, and the average protein intake was 207 grams (13.3 % of the total energy intake). The protein intake in this level has been shown to have no correlations with the size of adipose tissue (P>=0.464), but has a significant correlation with body size (weight and height) (P<0.0001). Additionally, the percentage of consumed protein at the age of 9th months was correlated with the percentage of protein and energy intake at the age of 10 years (r = 0.28 P=0.01). A 0.01% increase in the energy intake from protein at 9 months of age was associated with an increase of 0.44 kg in weight at 10 years of age (P=0.07). The weight at the age of 10 years was also associated with the total protein consumed at the age of 9 months (P=0.012). In our study, the results were different, particularly in the girls, where we observed a decrease in weight growth. In the study by Hoppe and colleagues, height at the age of 10 years was significantly correlated with the total protein intake (P=0.009) (14). An increase of 0.01% of energy intake from protein in the age of 9 months was related to increase in height at the age of 10 years (P=0.003). The finding of the mentioned study may justify our trial.Koletzko and co-workers (16) conducted an interventional study on 1138 newborns of cow milk-based formula, who were randomly selected from five countries. The group was consumed a low-protein diet (1.7 and 2.5 g of protein) (7.1%) and the other group consumed a high-protein diet (2.9 and 4.4 g of protein) (11.7%). The density of these formulas was equal to the fat. The ratio of protein to casein in all the formulations was 1.4. On the other hand, 619 breast-fed children were also examined. The receiving energy in the consumer groups of low-protein and high-protein formulas were the same. The received proteins were different between groups by the end of the study. Height, weight, and the body mass index of the two groups were monthly evaluated. They reported that the difference between weight, height, and weight for height and BMI between the high-protein and standard-protein groups started from the 6th month. The increase in these parameters in infants receiving breast milk was lower than that in the group receiving high-protein formulations. The height at 24 months was not different between these interventional groups. On average, weight gain after one year was 12.42 in low-protein group and 12.66 kg in high-protein group. The difference between the groups was not significant. Meanwhile, it was found that height was not different between groups. In general, the difference between the two formulation recipients regarding weight, weight for height, and BMI was greater at 1 year of age. Neonates with higher protein intake had higher weight, height for age, and BMI compared to standard growth charts. They reported that the increase in protein formulation was correlated with further weight gain but not height in the early life. In our study on different age groups, we found no differences concerning height growth between the high-protein group and low-protein group after 5 months. Our study was performed in a relatively short period. To date, there has not been a clinical study on the influence of high-protein foods consumption on the growth and weight of children with ADHD. This study was the first to test the effect of high-protein diet on the growth and weight of children with ADHD receiving Ritalin.

Limitations

One of the limitations of our study was the limited study duration. Furthermore, the implementation of any clinical trials is missing the patients and failure to follow the study protocol. To tackle this limitation, we closely monitored the subjects on regular monthly visits and via telephone to increase the compliance with their diet and study protocol. Moreover, we utilized intention-to-treat (ITT) analysis approach in analysis to reduce this limitation. The other limitation of our study was that we did not measure the physical activity level and appetite during the study.

5. Conclusion

Girls and boys responded differently to the HPD. Following 5 months consumption of HPD and compared to the control, boys had higher BMI and weight gain than girls, while the BMI and weight decreased significantly in girls. This may be due to the effects of HPD on the girls' appetite, as well as different body composition and different patterns of growth and puberty period in the two genders.

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Ethical Approval:

The acceptance and signature of a voluntary and informed consent form were required to contribute to the study. Furthermore, the participants were free to withdraw their consent at any stage of the research for any reason. All the participants received the standard care. The trial protocol was accepted by the Institutional Ethics Review Board (IRB) of Tehran University of Medical Sciences with the code of IR.TUMS.REC.1394.905 and conducted in accordance with the Declaration of Helsinki and subsequent revisions.

Name of the institution where the work was done: Psychiatry and Psychology Research Center, Roozbeh Hospital, Tehran University of Medical Sciences

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Conflict of Interests:

The authors declared no conflict of interest.

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