**ORIGINAL RESEARCH ARTICLE**

# Clinical effects of methylphenidate hydrochloride extended-release tablets on improvement of intelligence and behavior in children with attention deficit hyperactivity disorder

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## Abstract

This study aimed to investigate the impacts of methylphenidate hydrochloride extended-release tablets on intelligence and behavior in children with attention deficit hyperactivity disorder. One hundred and twenty children with attention deficit hyperactivity disorder admitted to Nanjing First Hospital, Nanjing Medical University, Nanjing, China from January 2023 to January 2025 were included and randomly divided into a control group and a study group. The study group adopted methylphenidate hydrochloride extended-release tablets. The control group adopted placebo. Compared with the control group, the study group had an increase in intelligence level scores, self-awareness scores and quality of life scores as well as a decrease in behavior scores and clinical symptoms scores following 12 weeks of treatment. Compared with the control group, 5-hydroxytryptamine, norepinephrine and dopamine levels in the study group were higher after 12 weeks of treatment. However, the above indicators showed no differences in the control group between before and after treatment. We conclude that methylphenidate hydrochloride extended-release tablets improve the intelligence level, attention and behavior problems, promote self-awareness and quality of life, and improve the levels of monoamine neurotransmitters in children with attention deficit hyperactivity disorder.. *(Afr J Reprod Health 2025; 29 [6]: 141-149).*

**Keywords:** Attention deficit hyperactivity disorder; children; methylphenidate hydrochloride prolonged-release tablet;, monoamine neurotransmitters

## Résumé

Cette étude visait à évaluer l'impact des comprimés de chlorhydrate de méthylphénidate à libération prolongée sur l'intelligence et le comportement d'enfants atteints de trouble déficitaire de l'attention avec hyperactivité (TDAH). Cent vingt enfants atteints de TDAH, admis au Nanjing First Hospital, Université de médecine de Nanjing, en Chine, entre janvier 2023 et janvier 2025, ont été inclus et répartis aléatoirement en un groupe témoin et un groupe d'étude. Le groupe d'étude a pris des comprimés de chlorhydrate de méthylphénidate à libération prolongée. Le groupe témoin a pris un placebo. Comparativement au groupe témoin, le groupe d'étude a présenté une augmentation des scores d'intelligence, de conscience de soi et de qualité de vie, ainsi qu'une diminution des scores de comportement et des symptômes cliniques après 12 semaines de traitement. Comparativement au groupe témoin, les taux de 5-hydroxytryptamine, de noradrénaline et de dopamine étaient plus élevés après 12 semaines de traitement. Cependant, les indicateurs mentionnés ci-dessus n'ont montré aucune différence entre le groupe témoin avant et après le traitement. Nous concluons que les comprimés de chlorhydrate de méthylphénidate à libération prolongée améliorent le niveau d'intelligence, l'attention et les troubles du comportement, favorisent la conscience de soi et la qualité de vie, et améliorent les taux de neurotransmetteurs monoamines chez les enfants atteints de trouble déficitaire de l'attention avec hyperactivité. *(Afr J Reprod Health 2025; 29 [6]: 141-149).*

**Mots-clés**: trouble déficitaire de l'attention avec hyperactivity; enfants, comprimés de chlorhydrate de méthylphénidate à libération prolongée, neurotransmetteurs monoamines.

## Introduction

Attention deficit hyperactivity disorder (ADHD) belongs to a common chronic neurodevelopmental disease during childhood[1]. Its common clinical symptoms include inattention, excessive activity, and reduced attention time[2]. ADHD children are often accompanied by poor academic performance, oppositional defiance, inability to focus on specific issues for a long time, inability to sit still for a long time, and frequent activity[3]. The etiology and pathogenesis of this disease are still unclear, but it is believed to be caused by the interaction of genetic and environmental factors[4]. The current clinical

treatment for ADHD children mainly includes drug treatment and non-drug treatment[5]. The former can improve the symptoms of attention deficit in children in the short term, reduce the situation of excessive activity, improve academic performance to a certain extent, and improve the adverse relationship between children and parents and classmates[6]. The latter mainly includes psychological treatment, parent training, and school intervention to solve a series of adverse effects caused by the disease through multi-party cooperation, and maximize the healthy development of children and return to normal life[7].

Methylphenidate hydrochloride extended-release tablets (MPH ERTs) are both commonly used in the treatment of ADHD children. They are central nervous system stimulants that improve neurotransmission in the brain by regulating the release and reuptake of neurotransmitters such as dopamine and norepinephrine, thereby improving attention and impulse control in children[9]. At present, there are few clinical studies on the clinical effect and safety of MPH ERTs in ADHD children[10, 11], and it remains unclear whether MPH ERTs can improve the intelligence and behavior of children with ADHD. Therefore, the objective of our study was to explore the clinical effects of MPH ERTs on improvement of intelligence and behavior in children with ADHD.

# Methods

A total of 120 ADHD children admitted to Nanjing First Hospital, Nanjing Medical University, Nanjing, China from January 2023 to January 2025 were included in this study. The inclusion criteria were: (1) children who met the diagnostic criteria for ADHD; (2) those who had not previously received treatment history (such as central stimulants, antidepressants) within one month before enrollment; (3) no abnormal liver or kidney function; (4) complete clinical data; (5) no allergy to the drugs utilized in this study. The exclusion criteria were: (1) patients with congenital genetic disease, brain organic disease; (2) those with cognitive impairment and serious mental illness; (3) neurodevelopmental delay, mental disorders; (4) allergic to the drug of this study. Children were randomly divided into the control group and study group, and each group had 60 children. The randomization process was performed using a computer-generated randomization table.

## *Treatment methods*

The study group accepted Methylphenidate hydrochloride extended-release tablets (Janssen-Cilag Manufacturing, LLC), the initial dose was 18 mg/time, once/day, the whole tablet was swallowed. After 2 weeks of continuous medication, the dosage was adjusted according to the clinical symptoms and tolerance of the children, and the medication was continued until 12 weeks.

The control group was given placebo (sugar pill with the same color, size and quality as MPH ERTs) over 12 weeks.

## *Observed indicators*

(1) Utilizing the Chinese Wechsler Intelligence Scale for Children (C-WISC), the children's intelligence level was assessed[12]. The test was evaluated by professional researchers, and the operational intelligence quotient (PIQ), verbal intelligence quotient (VIQ) and full-scale intelligence quotient (FIQ) scores were obtained by systematic analysis. According to FIQ evaluation, <70 was classified as intellectual disability, 70 to 79 as critical value, 80 to 89 as retardation, and ≥90 as normal.

(2) Utilizing the Chinese version of Swanson, Nolan and Pelham IV Scale (SNAP-IV), the children's behavior was assessed[13], including hyperactivity/impulsivity (total score 27), attention deficit (total score 24) and oppositional defiance (total score 24). The relationship between score and behavior was negatively correlated.

(3) Utilizing the Conners Parent Symptom Questionnaire (PSQ), the children's clinical symptoms were assessed[14]. This scale was filled in by the parents of the children, including 6 items of learning problems, behavioral problems, somatic problems, anxiety, impulsive-hyperactivity and hyperactivity index, with a total of 48 items. The 0-3 scoring method was used to reflect the behavioral and emotional problems of the children, with higher score representing more serious symptoms of children.

(4) Utilizing the Piers-Harris Children's Self-Concept Scale (PHCSS), the children's self-awareness was assessed[15]. There were 6 subscales,

involving children's intelligence, behavior, physical condition, anxiety, gregariousness, as well as happiness and contentment. The total score was 0 to 100 points, and a high score indicated that children had a good evaluation in this dimension.

(5) Utilizing the Pediatric Generic Core Quality-of-Life Inventory 4.0-Scale (PedsQL4.0) score, the children's quality of life was assessed[16], including physiological, psychosocial, emotional as well as role. The score of each item was 0 to 100 points, with higher score indicating better quality of life.

(6) Three ml of venous blood was collected from the children, the sample was centrifuged (3000 r/min, 10 min), and serum was obtained. The levels of 5-hydroxytryptamine (5-HT), norepinephrine (NE) and dopamine (DA) were determined by HPLC electrochemical method.

### *Statistical analysis*

GraphPad Prism 10.0 statistical software was employed for analyzing the data. The measurement data were exhibited by mean ± standard deviation (x±s), and t-test was conducted for comparison. The counting data were exhibited as number and rate (%), and $\chi^2$ test was applied for comparison. $P<0.05$ was considered as statistically significant.

### *Ethical consideration*

This study obtained the approval documents of the Ethics Committee of Nanjing First Hospital, Nanjing Medical University on December 21, 2022, and the approval number was KY20221216-03, and the informed consent of all the guardians of the children.

## Results

### *General data of children in both groups*

As shown in Table 1, there was no significant difference in general information of the children in the study and control groups (P>0.05).

### *Intelligence level of children in both groups*

Prior to treatment, the C-WISC scores in the aspects of PIQ, VIQ and FIQ showed no differences between the two groups (P>0.05). Following 12 weeks of treatment, the C-WISC scores in the above aspects were elevated in the study group, but those in the study group were higher when comparedwith the control group (P<0.05). The C-WISC scores in the above aspects showed no differences in the control group between before and after treatment (P>0.05, Figure 1).

### *Children's behavior in both groups*

Prior to treatment, the SNAP-IV scores in the aspects of hyperactivity/impulsivity, attention deficit and oppositional defiance showed no differences between the two groups (P>0.05). Following 12 weeks of treatment, the SNAP-IV scores in the aspects of hyperactivity/impulsivity, attention deficit and oppositional defiance declined in the study group, and those in the study group were lower when compared with the control group (P<0.05). The SNAP-IV scores in the aspects of hyperactivity/impulsivity, attention deficit and oppositional defiance showed no differences in the control group between before and after treatment (P>0.05, Figure 2).

### *Clinical symptoms of children in both groups*

Prior to treatment, the PSQ scores in the aspects of learning problems, behavioral problems, somatic problems, anxiety, impulsive-hyperactivity as well as hyperactivity index showed no differences between the two groups (P>0.05). Following 12 weeks of treatment, the PSQ scores in the above aspects declined in the study group, but those in the study group were significantly lower when comparedwith the control group (P<0.05). However, the PSQ scores in the above aspects showed no differences in the control group between before and after treatment (P>0.05, Figure 3).

### *Children's self-awareness in both groups*

Prior to treatment, the PHCSS scores in the aspects of intelligence, behavior, physical condition, anxiety, gregariousness, as well as happiness and contentment showed no differences between the two groups (P>0.05). After 12 weeks of treatment, the PHCSS scores in the aspects of intelligence, behavior, physical condition, anxiety, gregariousness, as well as happiness and contentment were elevated in the study group, but those in the study group were significantly higher when compared with the control group (P<0.05).

**Table 1:** General data of children in both groups

| Groups | Cases | Gender | | Age (years) | Course of disease (years) |
|---|---|---|---|---|---|
| | | Male | Female | | |
| Control group | 60 | 40 (66.67) | 20 (33.33) | 8.86±1.63 | 2.29±0.59 |
| Study group | 60 | 43 (71.67) | 17 (28.33) | 8.92±1.73 | 2.32±0.64 |
| $\chi^2$/t | | 0.35 | | 0.19 | 0.26 |
| P | | 0.55 | | 0.84 | 0.79 |

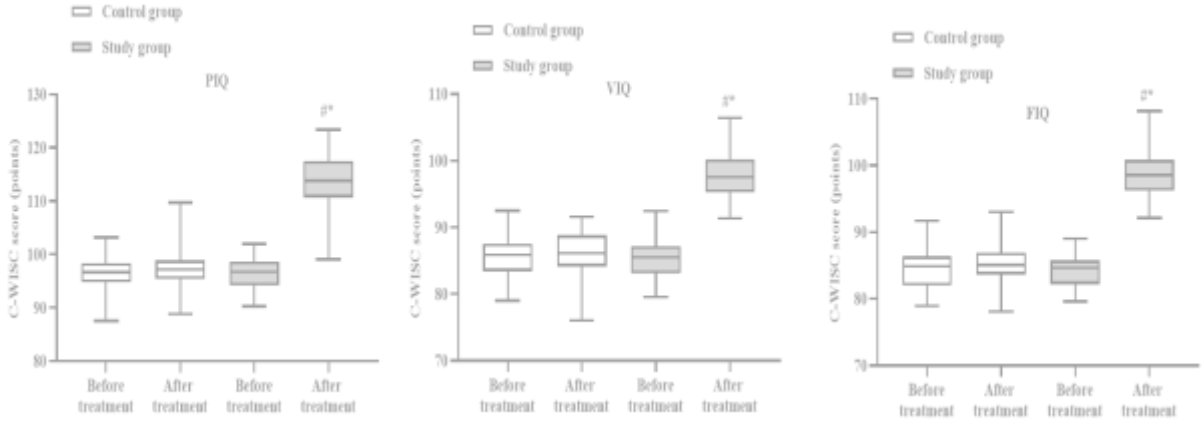


**Figure 1:** Intelligence level of children in both groups. #P<0.05, vs before treatment; *P<0.05, vs control group

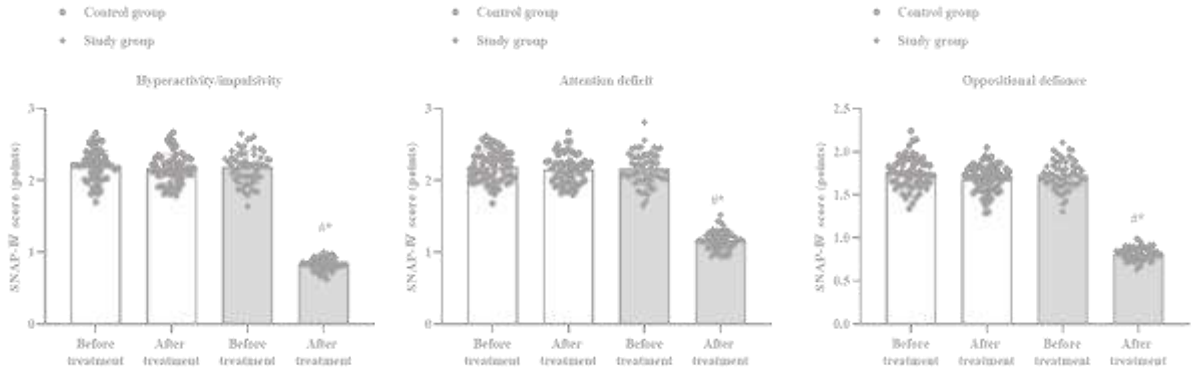


**Figure 2:** Children's behavior in both groups. #P<0.05, vs before treatment; *P<0.05, vs control group.

However, the PHCSS scores in the aspects of intelligence, behavior, physical condition, anxiety, gregariousness, as well as happiness and contentment showed no differences in the control group between before and after treatment (P>0.05, Figure 4).

## *Children's quality of life in both groups*

Prior to treatment, the PedsQL4.0 scores in the aspects of physiological, psychosocial, emotional and role showed no significantly differences between the two groups (P>0.05). Following 12 weeks of treatment, the PedsQL4.0 scores in the aspects of physiological, psychosocial, emotional and role were elevated in the study group, and those in the study group manifested higher when comparing with the control group (P<0.05). However, the PedsQL4.0 scores in the aspects of physiological, psychosocial, emotional and role showed no differences in the control group before and after treatment (P>0.05, Figure 5).

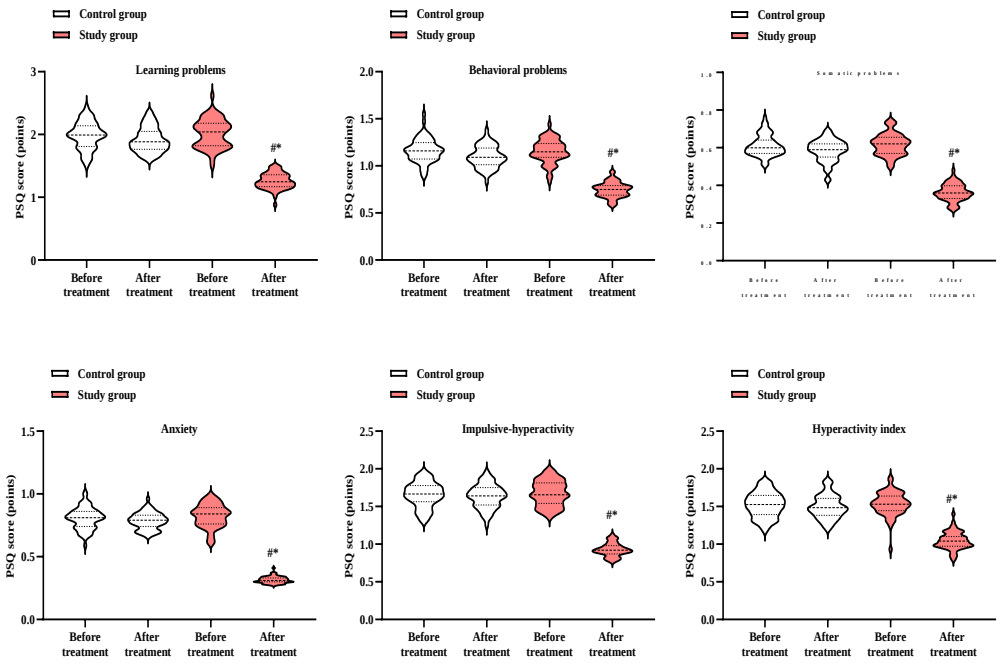


**Figure 3:** Clinical symptoms of children in both groups. #P<0.05, vs before treatment; *P<0.05, vs control group.

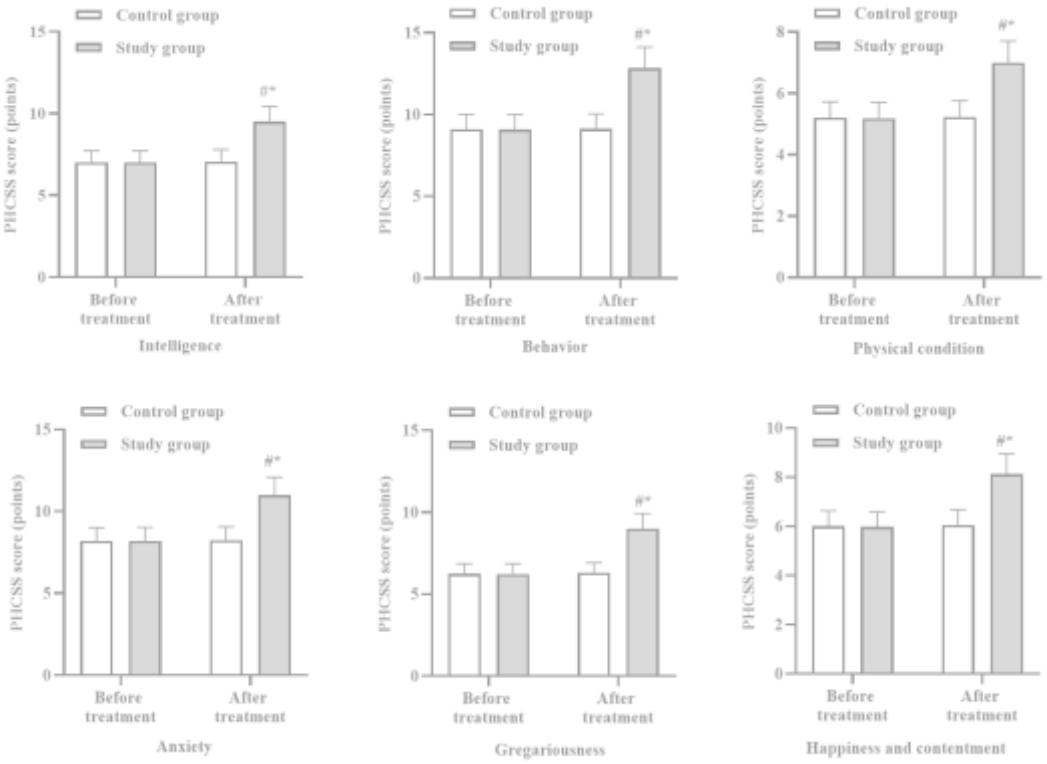


**Figure 4:** Children's self-awareness in both groups. #P<0.05, vs before treatment; *P<0.05, vs control group.

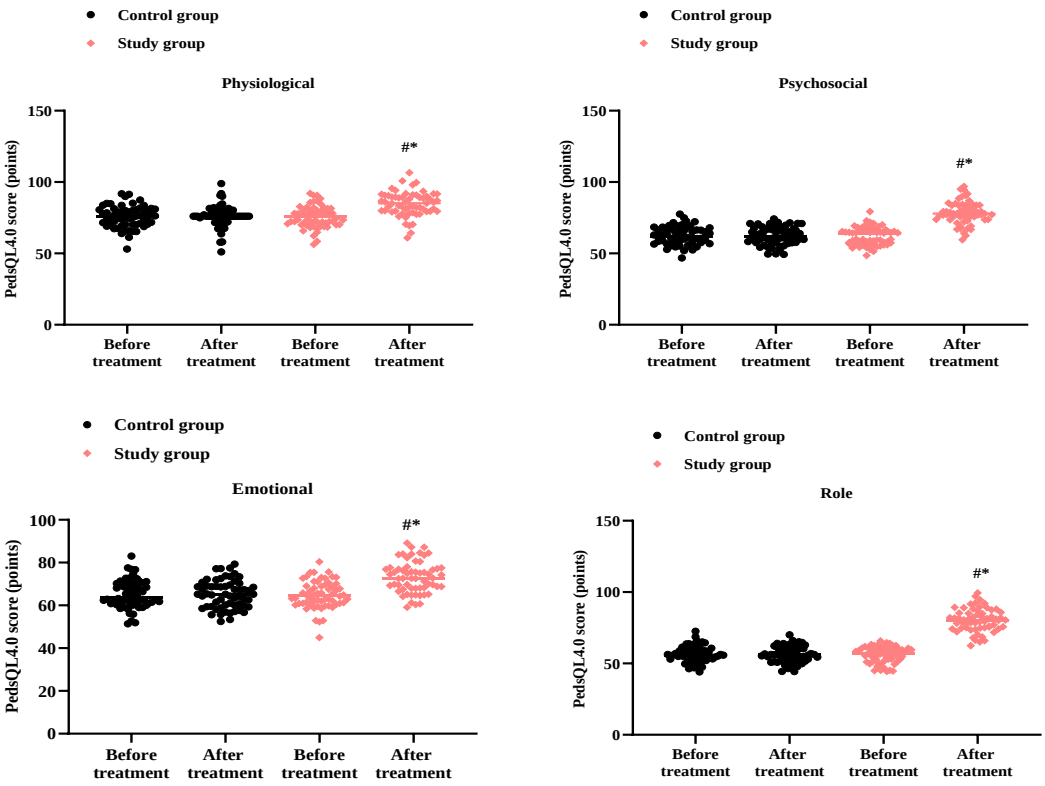


**Figure 5:** Children's quality of life in both groups. #P<0.05, vs before treatment; *P<0.05, vs control group.

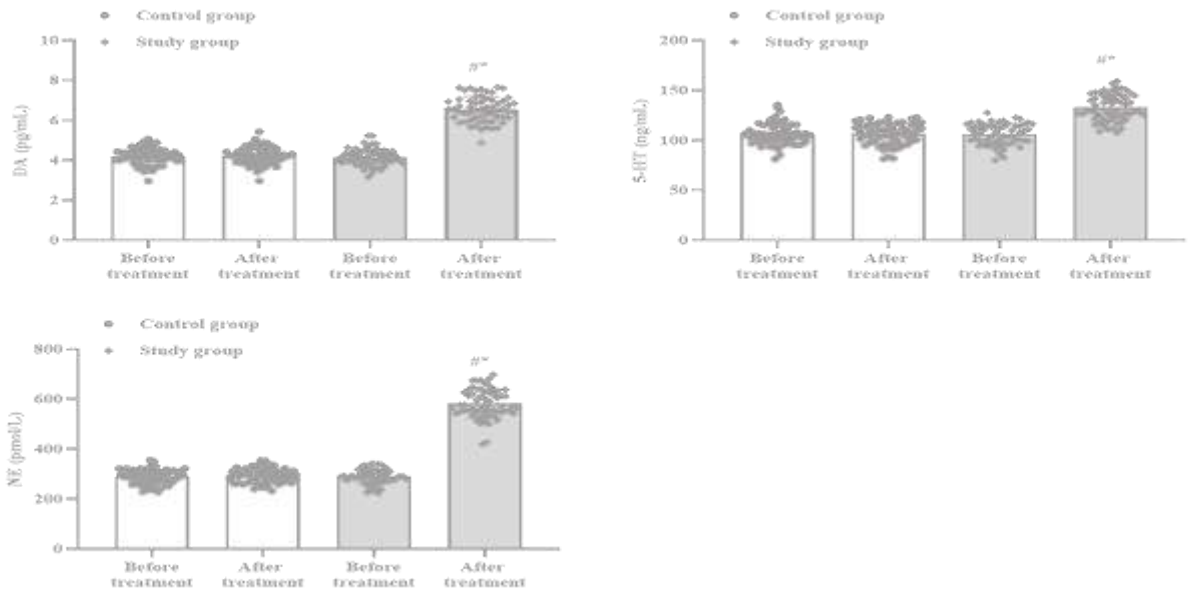


**Figure 6:** Levels of monoamine neurotransmitters in both groups. #P<0.05, vs before treatment; *P<0.05, vs control group.

### *Levels of monoamine neurotransmitters in both groups*

Prior to treatment, DA, 5-HT as well as NE levels showed no differences between the two groups (P>0.05). Following 12 weeks of treatment, DA, 5-HT as well as NE levels were elevated in the study group, but those in the study group were higher when compared with the control group (P<0.05). However, DA, 5-HT as well as NE levels showed no differences in the control group between before and after treatment (P>0.05, Figure 6).

## Discussion

ADHD belongs to a common childhood psycho-behavioral disorder that usually happens in childhood and may persist into adulthood in about 57% of children[17]. According to relevant data and statistics, the incidence of ADHD in children in China is appropriate 5.6%, and the incidence has been increasing year by year in recent years[18]. Children with ADHD often exhibit hyperactivity, inability to sit still, excessive talk or interjection, and lack self-control to restrain impulsive behavior, so they often have difficulty learning, completing tasks and following rules[19]. At the same time, studies have found that ADHD children have a higher risk of anxiety and depression than children without ADHD[20]. Therefore, the treatment of ADHD children is of great significance.

Our results showed that following 12 weeks of treatment, the study group had an increase in C-WISC scores, PHCSS scores and PedsQL4.0 scores as well as a decrease in SNAP-IV scores and PSQ scores, with better improvements in the study group when comparing with the control group, suggesting that MPH ERTs may be effective in improving intelligence level, attention and behavior problems as well as promoting self-awareness and quality of life in ADHD children. The reasons are as follows: MPH ERTs can promote the release of dopamine and inhibit its reuptake, thereby increasing the concentration of dopamine between neurons, helping to improve the normal communication between neurons, improve the ability to pay attention and regulate behavior[21]. In addition, MPH ERTs can also enhance the function of the prefrontal cortex, an area that plays an important role in attention and behavioral control[22]. Consistently, Childress *et al.* suggested that dose optimization of MPH ERTs led to a decrease in ADHD symptoms, indicated by a decrease in ADHD Rating Scale-IV (ADHD-RS-IV) score along with Clinical Global Impression-Improvement (CGI-I) scores[10]. Wigal *et al.* indicated that MPH ERTs significantly improved ADHD symptoms, and was generally safe and well tolerated[23].

Studies have found that the occurrence of ADHD is related to the abnormal metabolism of brain neurotransmitters, including NE, DA and 5-HT, caused by the retardation of brain frontal lobe[24]. DA is the most active neurotransmitter of catecholamines, which regulates neuronal activity related to emotion and movement, and can bind to DA receptors to participate in the regulation of memory and impulse type selection of the body[25]. It is found that DA is the key gene of ADHD and has an important role in ADHD[26]. NE is a neurotransmitter distributed in the pons and medulla oblongata, which has an important role in controlling the excitability and alertness of the whole brain during excitation[27]. Clinical studies have found that ADHD patients have abnormal NE levels, and the methylation of NE transporters and the expression level of NE transporters are significantly correlated with the symptoms of patients[28]. 5-HT is a monoamine neurotransmitter with a variety of complex functions, and its abnormal level is involved in the occurrence of a variety of psychiatric diseases[29]. It is believed that 5-HT is relatively insufficient in the central nervous system of children with ADHD, which is unable to filter out ineffective stimuli, resulting in children's indiscriminate response to various external stimuli, causing excessive activity[30]. The results of our study indicated following 12 weeks of treatment, DA, 5-HT as well as NE levels were elevated in the study group, and those in the study group manifested higher when comparing with the control group. All these results suggested that MPH ERTs could improve the levels of monoamine neurotransmitters in ADHD children. Consistently, it has been proved that the primary pharmacologic effect of MPH ERTs is to elevate central DA and NE activity, thereby affecting executive and attentional function[31].

There are some shortcomings in this study, such as a small number of children included, short observation time, and no consideration of the disease course, family environment, and psychological state

of children, which need to be further improved in subsequent studies.

## Strengths and limitations

This was a well-designed randomized trial intended to provide decisive evidence regarding the treatment of children with ADHD. Small sample size and no follow-up are the main limitation. Our study may provide a promising drug for ADHD treatment

## Conclusion

Our study demonstrates that MPH ERTs can improve intelligence level, attention and behavior problems, promote self-awareness and quality of life, and improve the levels of monoamine neurotransmitters in children with ADHD.

## Authors contribution

Wenjin Huang, Yanyan Wang: conceived and designed the study, collected and analysed the data, and prepared the manuscript. All authors mentioned in the article approved the manuscript.

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