

# Clinical Observation of Qibi Anshen (Opening-Blocking and Tranquilizer) Acupuncture Therapy Combined with Qibi Anshen (Opening-Blocking and Tranquilizer) Granules in the Treatment of Autism Spectrum Disorders

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**Abstract:** This paper aims to observe the clinical efficacy of Qibi Anshen acupuncture therapy combined with Qibi Anshen Granules on core symptoms and anxiety disorders in preschool children with mild to moderate Autism Spectrum Disorder (ASD). Sixty mild to moderate preschool children with ASD treated in Xi'an Encephalopathy Hospital, Shaanxi Province, from June to December 2023, were selected and divided into control and observation groups using SPSS 25.0 software, with 30 cases in each group. The control group was treated with behavioral analysis therapy combined with structured education, 2-3 h/d, for one month. Based on the control group, the observation group was given Qibi Anshen Granules and Qibi Anshen acupuncture therapy treatment. In conclusion, Qibi Anshen acupuncture therapy combined with Qibi Anshen Granules can alleviate the core symptoms of preschool children with mild to moderate ASD, improve their social communication ability, and improve their anxiety disorder, which is worthy of clinical application.

**Keywords:** Qibi Anshen Granules; Acupuncture therapy; Autism spectrum disorder

## 1. Introduction

Autism Spectrum Disorder (ASD) [1] is a neurodevelopmental condition that arises during infancy and is clinically manifested by social deficits and repetitive, stereotyped behaviors. Currently, there is no unified or standardized treatment protocol for preschool children with ASD, and due to their generally concealed and easily overlooked nature, these children often experience longer and more severe courses of the disease [2]. This study focuses on children with ASD categorized in traditional Chinese medicine as having "excessive heart and liver fire," administering oral Qibi Anshen Granules combined with Qibi Anshen acupuncture therapy, along with rehabilitation treatment, to observe changes in the children's conditions before and after treatment.

## 2. Clinic Data

### 2.1. Case Selection Criteria

Sixty preschool children with mild to moderate ASD who visited Xi'an Brain Disease Hospital in Shaanxi Province from June to December 2023 were selected and divided into a control group and an observation group using the Excel software Rand function, with 30 cases in each group.

#### 2.1.1. Diagnostic Criteria

Western medicine diagnoses standard :

The diagnostic criteria for ASD were referenced from the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) [3].

If the following A, B, C, and D criteria are met, the case can be diagnosed as ASD.

A. The social communication and social interaction deficits that persist in various scenarios cannot be explained by general developmental delay and meet the following three criteria.

(1) Social-emotional interaction deficiency: Mild individuals exhibit abnormal social contact and an inability to engage in back-and-forth conversations. Moderate manifestations include a lack of shared interests and emotions and decreased social responses. Heavy individuals are entirely unable to initiate social interactions.

(2) Defects in nonverbal communication behaviors used for social interaction: Mild cases manifest as difficulties in integrating verbal and nonverbal communication. Moderate symptoms include abnormal eye contact and body language or deficiencies in understanding and using nonverbal communication. The heavy ones completely lack facial expressions or gestures.

(3) Defects in establishing or maintaining interpersonal relationships that match their developmental level (excluding relationships with caregivers): Mild individuals exhibit difficulty adjusting their behavior to adapt to different social situations—moderate difficulty in playing imaginative games and making friends. The heavy ones have no interest in others.

B. Narrow and repetitive behavior, interests, or activity content, at least meet two criteria in the following.

(1) Stereotypes or repetitions of language, actions, or objects (such as simple stereotyped actions, echoic language, repeated use of objects, bizarre statements).

(2) Excessive adherence to a specific routine and verbal or nonverbal behaviors, or excessive resistance to change (such as athletic ritual behaviors, adhering to the same route or food, repeatedly asking questions, or feeling extreme pain for subtle changes).

(3) Highly narrow and fixed interests are abnormal in intensity and attention (such as strong attachment or addiction to unusual objects, excessive limitation, or sustained interest).

(4) Excessive or low response to sensory stimuli, showing abnormal interest in sensory stimuli in the environment (such as numbness to pain, heat, and cold, adverse reactions to certain specific sounds or materials, excessive sniffing or touching of particular objects, addiction to light or rotating objects).

C. The symptoms must appear in early childhood (but when the child's social needs do not exceed their limited abilities, the symptoms may not fully manifest or may be masked by the skills learned later on).

D. All symptoms collectively limit and impair daily function. (Bringing significant clinical obstacles in social, occupational, or other critical functional areas).

E. Symptoms cannot be explained by intellectual developmental disorders or delayed overall development. Intellectual developmental disorders and autism spectrum disorders often coexist, and only when their social communication level is lower than their overall developmental level can both autism spectrum disorders and intellectual developmental disorders be diagnosed simultaneously.

Chinese medical syndrome differentiation standards :

Referring to the Diagnostic and Therapeutic Standards for Traditional Chinese Medicine (TCM) [4], the TCM syndrome differentiation and classification of autism mainly include the type of heart liver fire hyperactivity.

Symptoms of heart and liver fire syndrome include avoiding eye contact, being restless, exhibiting self-directed behavior, running and jumping unpredictably, lack of self-control, challenging discipline, limited interests, stiff movements, impulsivity, easily irritated, inability to focus, speaking continuously, occasional yelling, high-pitched voice, mental hyperactivity, possibly insomnia, restlessness at night, sporadic constipation, yellow tongue with a red texture or sharp edge, thin yellow coating on tongue, stringy or rapid pulse, and purple fingerprints.

### **2.1.2. Inclusion Criteria**

First, the age range is from 3 to 7 years old. Second, according to the Children's Autism Rating Scale (CARS), it was assessed as mild to moderate ASD. According to the neuropsychological development test for children aged 0-6, the scores for adaptation and language ability areas are >75 points. The guardian has given informed consent to this research protocol and voluntarily signs an informed consent form.

### 2.1.3. Safety Indicators

General clinical data: Vital signs (body temperature, heart rate/rhythm, breathing, blood pressure).

Laboratory tests: blood routine, liver function (ALT, AST), kidney function (BUN, Cr).

Electrocardiogram examination.

Adverse reactions and events are recorded at any time.

### 2.1.4. Exclusion Criteria

Patients with childhood schizophrenia, Heller syndrome, or Rett syndrome. Patients with epilepsy. Patients with severe organic lesions, genetic metabolic diseases, and infectious diseases. Individuals who are allergic to drugs. Those who cannot persist in treatment. Subjects who meet any of the five criteria mentioned above will be excluded from this clinical study.

## 3. Methods

### 3.1. Treatment

Control Group:

We are combining behavioral analysis therapy with structured education. Including behavioral analysis therapy combined with structured educational methods for treatment. Train 2-3 hours a day and continue treatment for one month.

Observation Group:

Based on the control group, the patients were treated with Qibi Anshen Granules and Qibi Anshen acupuncture therapy. The specific treatment methods are as follows:

Qibi Anshen Granules: Composition: Radix Polygalae, Acorus calamus, Calcined Magnetite, Raw Osis Mastodi, lotus Plumule, Coptis Chinensis, Schisandra Chinensis, Radix Bupleuri, White Peony, Prepared Licorice Root. Dosage and administration: Take 50 mL warm water, administer one dose daily for seven consecutive days, and rest for three days. The dosage can be adjusted flexibly according to the patient's age, weight, and condition.

Acupuncture method: Use disposable stainless steel acupuncture needles with a diameter of 0.3 mm x 25 mm (Jiajian Medical Equipment Co., Ltd., Jiajian brand) and 0.13 mm x 2.0 mm disposable press needles. Main acupoint selection: Select Baihui, Sishencong, Shenting, Benshen, Renzhong, Yongquan, Shenmen, Neiguan, Fengchi, and Taichong as the main acupoints. Acupoint matching: For insomnia or insomnia, use Shenmai, Zhaohai, and Ansleep; Constipation with Tianshu and Zhigou; Leave a needle for 40 minutes per time, five days per week, and two days off per week

### 3.2. Observation Indicators

The psychological education assessment for children with autism (C-PEP-3) [5]: This scale includes seven aspects: imitation, perception, delicate movements, coarse movements, hand-eye coordination, cognitive performance, and oral cognition. The higher the score, the lighter the degree of psychological disorders. Evaluate the treatment effect of children with ASD; the higher the score, the more significant the impact.

The Childhood Autism Rating Scale (CARS) [6]: This scale consists of 15 items, each scored on a 4-level standard based on age-appropriate behavior, including regular, mild, moderate, and severe abnormalities. A score of  $\geq 30$  is considered a diagnostic score, with higher scores indicating more severe behavioral problems.

### 3.3. Efficacy Criteria

According to the standards of C-PEP-3 and CARS [7], the efficacy was evaluated by calculating the improvement rate of the C-PEP-3 score and the decrease of the CARS score using the Nimodipine method.

Significant effect: The improvement rate of the C-PEP-3 score is greater than 50%, and the total CARS score decreases by more than 3 points. Effective: The improvement rate of the C-PEP-3 score is

between 30% and 50%, and the total CARS score is reduced by 1-3 points (including 3 points). Invalid: The improvement rate of the C-PEP-3 score is less than 30%, and there is no change in the total CARS score.

### 3.4. Statistical Methods

Use SPSS 25.0 statistical software for data analysis. The quantitative data follows a normal distribution, represented by  $\bar{x} \pm s$ . Two independent sample t-tests are used for inter-group comparisons, and paired sample t-tests are used for intra-group comparisons. The count data is defined as [n (%)], using the chi-square or Fisher's exact probability test.  $P < 0.05$  indicates a statistically significant difference.

## 4. Result

### 4.1. Comparison of Gender and Age Between the Two Groups of Children

There was no significant difference in gender, age, and course of disease between the two groups ( $P > 0.05$ ). See Table 1.

Table 1: Comparison of gender and age between the two groups of children

Group	Number of Cases	Gender (Male & Female)/Case	Age (Years)/Case
Control Group	30 (Cases)	11 & 19	$5.21 \pm 1.03$
Observation Group	30 (Cases)	10 & 20	$4.91 \pm 1.25$
P-value	$>0.05$	$>0.05$	$>0.05$

### 4.2. Comparison of CARS Scores Between the Two Groups Before and After Treatment

There was no significant difference in CARS score between the two groups before treatment ( $P > 0.05$ ). After treatment, the CARS scores of the two groups decreased when compared with those before treatment, with significant differences ( $P < 0.01$ ). After treatment, the CARS score of the treatment group was significantly lower than that of the control group, and the difference was statistically significant ( $P < 0.05$ ). See Table 2.

Table 2: Comparison of CARS total scores between the two groups before and after treatment

Group	Number of Cases	Before Treatment (Cases)	After Treatment (Cases)	P-value
Control Group	30 (Cases)	$39.17 \pm 2.93$	$35.49 \pm 3.15$	$<0.05$
Observation Group	30 (Cases)	$39.53 \pm 2.78$	$32.57 \pm 3.27$	$<0.05$

### 4.3. Comparison of C-PEP-3 Scores Between the Two Groups Before and After Treatment

After one treatment course, the two groups' clinical effects were compared. The total effective rate of the treatment group was higher, and the difference was statistically significant ( $P < 0.05$ ). See Table 3.

Table 3: Comparison of CARS total scores between the two groups of children before and after treatment

Group	Number of Cases	Before Treatment (Cases)	After Treatment (Cases)	P-value
Control Group	30 (Cases)	$26.58 \pm 1.31$	$45.64 \pm 2.28$	$<0.05$
Observation Group	30 (Cases)	$27.26 \pm 1.54$	$36.51 \pm 2.13$	$<0.05$

### 4.4. Comparison of Efficacy Between the Two Groups of Children

After one treatment course, the two groups' clinical effects were compared. The total effective rate of the treatment group was higher, and the difference was statistically significant ( $P < 0.05$ ). See Table 4.

Table 4: Comparison of efficacy between the two groups of children (%)

Group	Number of Cases	Manifestation (Cases)	Effective (Cases)	Ineffective (Cases)	Total Effective Rate (%)
Control Group	30	23	5	2	93.33
Observation Group	30	15	10	5	83.33

## 5. Conclusion

In traditional Chinese medicine, the differentiation of syndromes and the treatment of ASD are based on the principles of Zang-Fu organs, Yin-Yang, and the essence of qi, blood, and body fluids. It is believed that ASD arises from the imbalance of Zang-Fu organ functions and Yin-Yang, stemming from congenital deficiencies, kidney essence depletion, and inadequate postnatal nourishment, which leads to insufficient essence and blood, inadequate nourishment of the brain and spirit, impaired liver function, and ultimately, malfunctioning of the spirit. The disease mainly affects the brain but is closely related to the heart, spleen, liver, and kidneys. In addition to congenital deficiencies and neonatal-specific conditions, children often exhibit "fragile lungs prone to illness, weak spleen easily injured, hot heart prone to fright, overactive liver prone to convulsions, and frail kidneys prone to damage." Cognitive impairments, among other symptoms, characterize ASD. Overall, the pathogenesis of ASD involves disorder and insufficiency of the brain's spirit, which is also associated with the heart, liver, spleen, and kidneys. However, some scholars, like Guo Jia[8], hold a different view, arguing that "congenital deficiency and kidney essence depletion" do not necessarily cause ASD. Instead, they propose that ASD involves primary liver dysfunction, with sleep disorders being a characteristic symptom and gastrointestinal dysfunction being another manifestation. Thus, ASD may stem from congenital "liver qi stagnation." As stated in "Ling Shu-Ben Shen," "the soul travels with the spirit," and "the liver is the general officer, where strategic plans originate." When the liver's dispersing and regulating function is impaired, it can lead to the malfunctioning of the spirit and abnormal behaviors.

The Qibi Anshen Granules [9] formula has the effects of awakening consciousness, calming the mind, enhancing mental clarity, and improving attention. It also possesses sedative, hypnotic, and anti-convulsant properties. The principal herbs, Radix Bupleuri, Gouteng, Shichangpu, and Radix Polygalae, harmonize the liver and soothe the spirit. The assistant herbs, Coptis Chinensis, Gentiana Root, Gardenia Fruit, Poria Cocos with Pith Removed, and Ziziphus Jujuba Seed, clear liver fire and nourish the heart. The adjuvant herbs, Os Draconis, Calcined Oyster Shell, White Peony, Salviae Miltiorrhizae Radix and Rhizoma, Turtle Plastron, and Lodestone further calm the spirit and soothe the liver. Prepared Licorice Root serves as the guiding herb to harmonize the overall formula. Together, they purify the heart and liver, stabilize the mind, and achieve the overall effect of awakening consciousness and calming the spirit. In clinical application, adjustments can be made based on individual symptoms for syndrome differentiation and treatment.

Modern medical research suggests that the variation in lateralization of cerebral hemisphere functions may be a crucial factor in the onset of mental disorders [10]. In traditional Chinese medicine, the brain is regarded as the "seat of the primal spirit" and the head as the "seat of wisdom and clarity," primarily governing consciousness, language, thought, memory, and emotions. Scalp acupuncture [11], based on functional localization of the cerebral cortex, treats brain-related disorders. It is combined with specific acupoints to soothe the liver, calm the mind, and regulate internal organs, aiming to balance yin and yang and address the root cause. Its primary effects include harmonizing the five internal organs, balancing yin and yang, calming the mind, and nourishing the will.

Incorporating rehabilitation education [12] into the treatment of ASD children can encourage their participation in activities, where, through observation and learning, abnormal behaviors can be reduced, and regular habits and behaviors can be established. This approach enhances their adaptability and communication skills. Additionally, studies and training [13] have shown the potential to alter neuronal responses, indicating that the brain remains plastic and responsive to intervention. Early education and exposure to enriched environments [14] play a vital role in promoting neuropsychiatric development in children, fostering a positive impact on their overall growth and development.

As indicated in the above table, post-treatment, the CARS and C-PEP-3 total scores of patients significantly surpassed those of the control group, with a higher overall treatment effectiveness. This study found that the combined therapy of Bi'an Shenzhen acupuncture and Qibi Anshen Granules

significantly reduced relevant examination indicators compared to the control group, presenting a novel treatment approach for preschool children with mild to moderate Autism Spectrum Disorder (ASD). However, due to the limited sample size, further clinical studies are needed to accumulate substantial clinical data.

Chinese medicine emphasizes holistic treatment and syndrome differentiation. ASD symptoms are complex and diverse, affecting multiple organs. This study leverages traditional Chinese medicine principles, using Qibi Anshen Granules combined with acupuncture to regulate organ functions. By harmonizing the body's organs and achieving "yin and yang balance, the spirit is nourished," we improve patients' quality of life through holistic treatment and syndrome differentiation. Combining herbal medicine and rehabilitation education enhances functional training, yielding significant results with no notable adverse effects.

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