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Seven-Star Needle Stimulation Improves Language and Social Interaction of Children with Autistic Spectrum Disorders

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Abstract: This is a randomized controlled trial that aimed to evaluate the effect of the Seven-star Needle Stimulation treatment on children with Autistic Spectrum Disorders (ASD). Thirty-two children with ASD were assigned randomly into the treatment and control groups. Children in the treatment group underwent 30 sessions of stimulation over 6 weeks, while children in the control group were on a waiting list and did not receive treatment during this period of time. Intervention consisted of a treatment regime comprising of 30 sessions of Seven-star Needle Stimulation, delivered over 6 weeks. Each session lasted 5 to 10 min, children in the treatment group were stimulated at the front and back sides of their body and the head by using Seven-star Needles. The change in the children's behavior was evaluated using parents' report and neurophysiological changes were measured by quantitative EEG (qEEG). Results showed that the treatment group demonstrated significant improvement in language and social interaction, but not in stereotyped behavior or motor function, compared to the control group. qEEG spectral amplitudes in the treatment, but not in the control group, were also reduced significantly. The results suggested that Seven-star Needle Stimulation might be an effective intervention to improve language and social functioning of children with ASD.

Keywords: Autistic Spectrum Disorders; Language; Social Communication; Seven-Star Needle Stimulation; Alternative Therapy; Quantitative Encephalography; Randomized Controlled Trial.

Introduction

Autistic Spectrum Disorder (ASD) is a lifelong developmental disorder characterized by poor social interaction with others, language delay or impairment, repetitive and stereotyped

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behavior. The prevalence rate of ASD ranges from 3.3 to 16 per 10,000 individuals (Bertrand *et al*., 2001; Fombonne, 2001; Hyman *et al*., 2001; Magnusson and Saemundsen, 2001; Wing, 1993). It is not only the prevalence rate that is relatively high, epidemiologic evidence also shows that the incidence rate has increased progressively in recent years (Hyman *et al*., 2001; Magnusson and Saemundsen, 2001; Wing, 1993; Chakrabarti and Fombonne, 2001). Though ASD is a common neurodevelopmental disorder affecting children worldwide, no cure has yet been found.

In the absence of effective pharmacological treatment (Carey *et al*., 2002), conventional intervention has been focused on educational training. Studies have reported positive effects of intensive and structured behavioral treatment on improving some aspects of autistic symptoms, including eye-to-eye gaze, communication and social interaction (Bauminger, 2002; Kravits *et al*., 2002; Panerai *et al*., 2002; Williams *et al*., 2002). While educational programs have been found to be effective in improving the behavior and language of children with ASD, these programs tend to be intensive in terms of time and human resources. For instance, in a recent study on the benefit of the TEACCH program, subjects were requested to reside at an institute for one year (Panerai *et al*., 2002).

Given that interventions often require an extensive number of hours and even years, some researchers have begun to investigate the effectiveness of alternative methods that may consume less time and labor (Escalona *et al*., 2001; Field *et al*., 1997; Mullins and Christian, 2001). For instance, Field and colleagues (1997) reported positive effects of massage therapy on a group of children with ASD. After eight 15-min sessions of touch therapy for over 4 weeks, the children demonstrated less touch aversion and stereotyped behaviors. Their social relatedness was also improved during classroom observation. These results were replicated when the massage therapy was performed by mothers of the children (Escalona *et al*., 2001). Their study showed that children who received massage therapy, compared to children in the control group who received attention training, demonstrated more attentive and on-task behavior at school. These studies provided some evidence suggesting that touching the skin of children with ASD has positive therapeutic effects, therefore, Seven-star Needle Stimulation therapy was designed for children with ASD aiming to reduce their clinical symptoms.

Seven-star Needle Stimulation has been used for over 1,000 years in China as a method of treatment for physical problems. One of the principles of Chinese medicine emphasizes the connection and harmony of the body in which the external "skin" is closely related to the internal "organs." Therefore, stimulation of the skin has been used as a way to stimulate internal organs to restore balance in the body. Different methods of intervention on the skin have been developed in China, including applying pressure on the skin, suctioning the skin with vacuum cups, applying herbal plasters on acupoints, and using Qi-gong to balance the flow of energy. Some methods are quite painful and others are relatively time intensive (e.g., 1 hour), thus may not be easy to apply on children. The method used in the present study was specially designed for children, where the sensations on the skin and the duration of the treatment are acceptable for most children.

A dermatoneural medical hammer (Fig. 1), used for housing the Seven-star Needles, was designed by the first author based upon the instrument described by Sun (1969). The hammer consists of 2 parts. The first part is a 13-inch rod assembled by 2 pieces of plastic sticks.

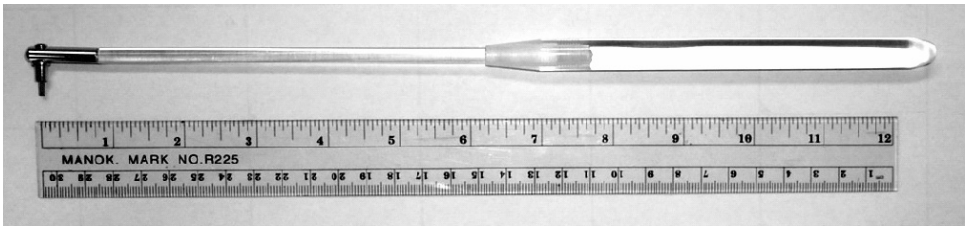

Figure 1. Dermatoneural medical hammer.

One end serves as the handle and the other to hold the head. The material allows flexibility and durability, and its shape was designed for stable gripping at a specific angle. The head part of the hammer consists of 7 blunt needles (5 mm long) forming the shape of a seven-point star. The bundle of needles can be detached easily for sterilization. Disposable needles were used and they are all identical with 1 mm diameter and 48 degree of sharpness. The size, the angle and the arrangement were specially designed so that it can provide maximum stimulation without penetrating the skin. Under the strength normally applied in the stimulation, the needles puncture a depth of about 0.5–1.0 mm onto the skin. Given that the thickness of the skin is about 5 mm, this type of stimulation will not cause bleeding.

One study had been done by using this dermatoneural medical hammer on a patient with chronic cerebellar hemorrhage with brain stem compression who presented with severe ataxia, gait imbalance and limb spasticity (Chan *et al*., 2003). After an 8-month intervention, the patient's function had improved by 40% in ataxia and hypotonia, suggesting that this method is effective as a neurologic intervention.

Two underlying mechanisms might explain the therapeutic effect of the Seven-star Needle Stimulation. The first is based on the traditional Chinese medicine concept that there are 20 channels distributed over the human body, and the channel on the front (Ren Channel) and the one on the back (Du Channel) govern all the organs and are especially vital. Stimulating these 2 channels will restore the harmony of the body, including the brain. The other hypothesis suggested that the treatment effect of Seven-star Needle Stimulation is related to the stimulation of the sympathetic nervous system distributed along the spine (Bai, 1989). Whether or which of these 2 hypotheses can better explain the underlying mechanism of the treatment remains to be tested empirically.

Based on traditional Chinese medicine and the study showing the therapeutic effect of Seven-star Needle Stimulation on a patient with chronic cerebella hemorrhage, we hypothesized that children undergoing the Seven-star Needle Stimulation would improve their behavioral symptoms, as well as altered qEEG profiles, compared to children in the control group.

Methods

Participants

Thirty-two children with ASD participated on a voluntary basis. They were recruited through advertisements sent to special educational centers in Hong Kong. The study was approved

by the Joint CUHK-NTEC Clinical Research Ethics Committee, and conducted according to the Declaration of Helsinki. Written consents were obtained from the parents of all children. The 32 children were randomly assigned into the treatment and the control groups. The treatment group received Seven-star Needle Stimulation treatment for 6 weeks, after which the control group received the same treatment. The 2 groups were matched in age (Treatment: Mean = 6.85, SD = 1.76; Control: Mean = 6.89, SD = 1.77), IQ (Treatment: Mean = 84.06, SD = 15.75; Control: Mean = 86.82, SD = 19.91) as measured by the Test of Nonverbal Intelligence (TONI; Brown *et al*., 1992), and gender distribution (boys = 13, girls = 3). All children were assessed twice, first at baseline before the treatment group started Seven-star Needle Stimulation, and at 6 weeks immediately after treatment ended. All parents received brief feedback on their children's cognitive functioning when they had successfully completed the study.

Procedures

Children in the treatment group underwent treatment 5 days per week for 6 weeks, receiving a total of 30 treatment sessions. Each session lasted 5 to 10 min. During the session, the therapist applied Seven-star Needle Stimulation on the child by tapping the skin quickly (approximately 20 times per 5 sec) with the dermatoneural medical hammer. The stimulation was performed on the 2 sides on the child's back along the spine (about half an inch on each side) from the lumbar to the thoracic region, along the midline on the front side of the body, and also on the dorsal and the posterior parts of the head. Each stimulation site was tapped 3 times, with a distance of about 2 cm between each tap. This stimulation pattern was developed primarily from clinical observation and the experience of Dr. Sun; the underlying nature of its therapeutic effect remains unclear.

Assessments

Children in both groups were assessed before and after the treatment group underwent Seven-star Needle Stimuation, that is, first at baseline and then 6 weeks later. They were assessed by parent's rating on 3 major areas that characterized children with ASD: language, social interaction and behavioral problems; as well as motor functioning. In addition, their change in quantitative electroencephalography (qEEG) profile was assessed to serve as a relatively objective outcome measure.

Parent's Rating Questionnaire: A specially designed questionnaire with 27 questions measuring 4 areas was developed for this study. A self-developed questionnaire was used instead of existing instruments as it was more preferable to have a tailor-made instrument to measure effects specific to our treatment. Ten questions were used to measure the child's language (e.g., length of the sentence, expressive ability), 7 questions on social interaction (e.g., eye contact with strangers, nonverbal expression), 8 questions on stereotyped behavior (e.g., obsessive behavior, repetitive behavior), and 2 questions on motor functioning (e.g., jumping, holding a pencil). The questionnaire was administered to the parents of both groups of children at the end of the treatment period. The scale ranged from −5 to 5 with 0 indicating

no change compared to 6 weeks ago. Negative scores indicated deteriorated performance and positive scores indicated improved performance, with larger numbers indicating greater magnitude of changes.

Quantitative Electroencephalogram (qEEG): qEEG data was collected by using the Brain-Master System Type 2E Module and software, with one channel output at the *FpZ* located in the middle between *Fp1* and *Fp2* (International 10–20 System of electrode placement (Andreassi, 1989), using the 2 ears as ground and reference. Data were collected in the eyes-open resting condition for 6 continuous min. The signals were segmented into six 1-min sessions by the recording software, and filtered to give digitized data for 5 frequency bands — Delta (1–3 Hz), Theta (4–7 Hz) Alpha (8–12 Hz), Beta (15–20 Hz), and High Beta (20–38 Hz). For each frequency band, mean amplitudes were calculated for each of the 6 one-min sessions, resulting in 6 mean amplitudes for each frequency band. A trained research assistant, blind to the children's group assignment, screened the raw waveforms, and selected the one-min that contained the longest duration of artifact-free signal to represent the qEEG for each child for the 5 frequency bands. The recording software has a built-in detector for artifacts which were automatically excluded from the data.

Results

Parents' Rating Questionnaire

All parents returned their rating questionnaires giving a response rate of 100%. Independent samples t-test (Table 1) showed that parents of the treatment group (Mean = 0.97, SD = 0.73) reported significantly greater overall improvement observed in their children than parents of the control group (Mean = 0.41, SD = 0.41, $t(30) = 2.66$, $p < 0.05$). Among the 4 domains, improvement was significantly greater for the treatment group in language and social interaction. The language score for the treatment group (Mean = 1.21, SD = 0.73) was significantly higher ($t(30) = 3.87$, $p < 0.01$) than that of the control group (Mean = 0.43, SD = 0.35). The score in social interaction for the treatment group (Mean = 1.07, SD = 0.77) was also significantly higher ($t(30) = 2.86$, $p < 0.01$) than that of the control group (Mean = 0.42, SD = 0.49). Item analysis on the language and social interaction scales

Table 1. t-Test Results on Mean Parent Ratings for the 4 Subscales

Subscale	Group				t-Test	
	Treatment (n = 16)		Control (n = 16)		t-Value	Effect Size
	Mean	SD	Mean	SD		
Language	1.21	0.73	0.43	0.35	3.87**	1.37
Social interaction	1.07	0.77	0.42	0.49	2.86**	1.01
Stereotyped behavior	0.55	1.08	0.34	0.67	0.67	0.24
Motor functioning	1.03	1.15	0.59	0.71	1.30	0.46
Overall	0.97	0.73	0.41	0.41	2.66*	0.94

*$p < 0.05$, **$p < 0.01$.

further revealed significant improvements (p's < 0.05) on eight items, that included more eye-contact with known individuals and with strangers, improved interaction with relatives and friends, and more facial expression. Language has improved in terms of the length of sentences, the clarity and frequency of speech.

Quantitative Electroencephalogram (qEEG)

Among the 32 children, 16 children either did not comply with the EEG recording procedure, or there were too many movements during the recording session to produce useful data for analysis. As a result, qEEG measurements were obtained from 16 children (9 in the control group and 7 in the treatment group). qEEG for 5 bands (Delta, Theta, Alpha, Beta and High Beta) were analyzed separately with repeated measures ANOVA, with *Group* as between-subject factor and *Assessment* (pre- and post-treatment) as within-subject factor (Table 2).

The *Group* by A*ssessment* interaction effect was found to be significant for Delta ($F(1, 14) = 5.22$, $p < 0.05$), Theta ($F(1, 14) = 5.20$, $p < 0.05$), Beta ($F(1, 14) = 5.43$, $p < 0.05$), and High Beta ($F(1, 14) = 7.04$, $p < 0.05$). The Alpha band was the only frequency band that did not show significant interaction effect. Post-hoc *t*-tests revealed that the control group showed positive changes in 4 of the 5 frequency bands, while the treatment group showed negative changes in 4 of the 5 bands. The respective percentage changes of the 5 bands are shown in Fig. 2. The results showed that the treatment group had a significant drop in amplitudes in 4 of the 5 bands compared to the control group (Delta: $t(14) = 2.19$, $p < 0.05$; Theta: $t(14) = 2.28$, $p < 0.05$, Beta: $t(14) = 2.90$, $p < 0.05$; High Beta: $t(14) = 2.83$, $p < 0.05$). Consistent with the results of the repeated measures ANOVA, children in the 2 groups did not demonstrate significant change in their alpha band.

Table 2. Spectral Amplitudes in the Pre- and Post-Assessments for the Control and Treatment Groups

	Control (n = 9)				Treatment (n = 7)			
	Pre-		Post-		Pre-		Post-	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Delta*	178.20	38.81	197.34	51.35	244.80	86.32	165.77	81.61
Theta*	78.73	16.90	73.80	12.21	107.71	31.90	70.50	15.62
Alpha[a]	45.62	12.21	43.36	6.35	61.86	26.66	49.89	13.44
Beta*	20.20	4.60	28.93	9.68	33.71	17.16	26.61	13.82
High Beta*	24.19	3.68	29.54	13.47	34.23	18.51	18.76	7.58

Repeated measures ANOVA (Group × Assessment) was performed on the data. *Denotes significant *group* × *assessment* interaction effect ($p < 0.05$); [a]Denotes significant *group* main effect ($p < 0.05$).

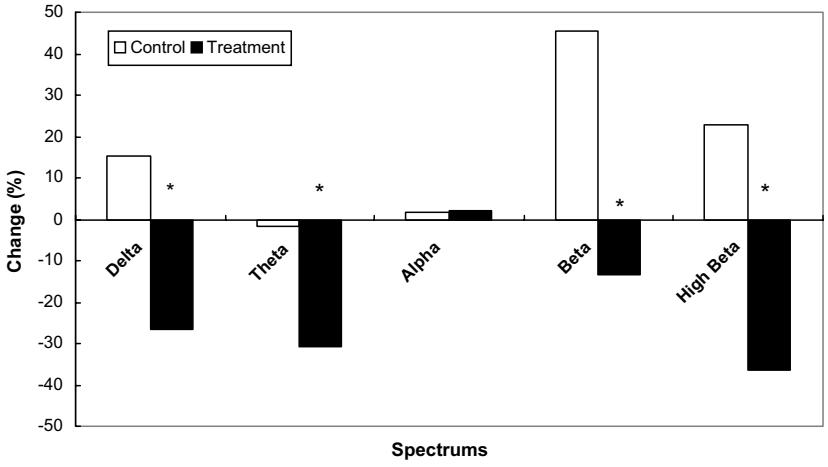

Figure 2. Percentage changes in amplitudes for the 5 spectrums in the pre- and post-assessments for the control and treatment groups. *$p < 0.05$.

Discussion

The present results provided some initial data suggesting that Seven-star Needle Stimulation with the dermatoneural medical hammer was effective in improving some aspects of language and social interaction in children with ASD. Specifically, children who underwent treatment demonstrated significant improvement in verbal expression and interaction with others, as reported by the parents. However, it should be noted that not all language and behavior problems were reduced. The relatively small extent of the effects observed in the present study may be related to the short duration of the treatment, since it usually takes 6 to 9 months for a more clinically significant treatment effect to be observed (based upon clinical experience). However, 2 cases from the treatment group might provide some information on the potential of this treatment. The first case was a 6-year-old child with ASD who was unable to write from A to Z before the treatment, but became able to write the entire alphabet after 3 months of treatment; the child was able to write in full sentences after 6 months. The second case was a child who was not able to speak with 2-word sentences before the treatment, but became able to speak in full sentences (more than 8 words) after 1 year of treatment.

While longer treatment duration might produce a more pronounced effect, it might create confounding factors that might affect the results, such as failure to follow-up, or other developmental factors. Thus, 30 sessions was considered the shortest duration for the treatment effect to be detected, while the possibility of confounding from other time-related factors was minimized. Under this constraint, the present study aimed at examining whether Seven-star Needle Stimulation is effective in reducing language and behavior problems in children with ASD, rather than exploring the maximum effect of this treatment. In light of these and other successful cases, the present study served as an initial scientific investigation to demonstrate experimentally the therapeutic effect of Seven-star Needle Stimulation on children with ASD. Further studies to assess the potential and extent of the effect are needed.

While there was a possibility that the parent ratings may be biased given that the parents were aware of the group assignment, the fact that improvements were observed in some but not all areas suggested that bias, if any, might not have been very serious. In addition, physiological data as measured by qEEG, which is a measure of the neural processing of the brain, provided relatively objective evidence to support that there is indeed a treatment effect of this therapy. The significant changes in qEEG profiles observed after the treatment seem to suggest that Seven-star Needle Stimulation is able to alter the information processing of the brain. Some studies reported that abnormal qEEG profiles were associated with various brain disorders, such as ASD (Cantor *et al.*, 1986; Chan and Leung, 2006; Chan *et al.*, 2007; Daoust *et al.*, 2004; Dawson *et al.*, 1995), attention-deficit/hyperactivity disorder (Lubar *et al.*, 1995a), brain lesions (Grummich *et al.*, 1995; Vieth *et al.*, 1995), and even with genetic locus (Projesz *et al.*, 2002). In addition, it has been reported that changes in EEG were associated with reductions in abnormal behavior (Lubar *et al.*, 1995b; Egner and Gruzelier, 2001; Kim *et al.*, 2002; Rossiter and La Vaque, 1995), such as improvement in attention was associated with decrease in Theta and increase in Beta in children with attention-deficit/hyperactivity disorder (Rossiter and La Vaque, 1995; Lubar *et al.*, 1995a). Thus, the change of qEEG profile on children with ASD in the present study suggests that Seven-star Needle Stimulation may be able to change the physiological functioning of the brain in children with language and behavior problems.

Although the present findings suggested that Seven-star Needle Stimulation is effective in improving the language and behavior of children with ASD, it is important to note that we do not recommend that conventional educational intervention be replaced. In fact, from the clinical experience of the first author, children with intensive home training have demonstrated more improvement in language and social functions than those without home training. Although there is no empirical data to demonstrate an interaction effect of Seven-star Needle Stimulation and educational programs on children with ASD, this is a reasonable expectation because Seven-star Needle Stimulation is intended to restore the harmony of the neural system, which in turn helps to improve the learning ability of the children. Improving children's learning ability without giving them appropriate training is not likely to result in better behavioral or academic performance. However, this hypothesis remains untested.

Although the present study produced some encouraging results, it is limited by the small sample size and short duration of treatment. The fact that qEEG data were obtained from only half of the participants, and the use of a self-developed questionnaire instead of one adapted from standardized instrument should also be kept in mind when interpreting the findings. Thus, the present study serves more as a starting point than a conclusion, to open up new lines of research to examine Seven-star Needle Stimulation in specific and traditional Chinese medicine in general, as complementary interventions for children with ASD.

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