

## Comparison of Auricular Therapy with Sham in Children with Attention Deficit/Hyperactivity Disorder: A Randomized Controlled Trial

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### Abstract

**Objectives:** Several studies have shown the clinical effects of auricular therapy for some neuropsychological disorders. The aim of this study is to compare the effectiveness of auricular therapy with the sham procedure in attention deficit hyperactivity disorder (ADHD).

**Design:** Randomized sham-controlled trial.

**Settings/Location:** Welfare Centers of Tehran (Iran).

**Subjects:** Fifty children with ADHD (6–14 years old).

**Interventions:** Patients were randomly assigned into two groups to receive either auricular therapy (Group A) or a sham procedure (Group B) once a week for 6 weeks.

**Outcome measures:** The Children Symptom Inventory (CSI-4) and the parent's version of the Conners Comprehensive Behavior Rating Scale were used to assess the severity of symptoms of attention deficit (AD) and hyperactivity (HA). Outcome evaluation data was obtained at the first and seventh weeks after the interventions. Data were analyzed by SPSS software using Friedman and Mann–Whitney *U* tests.

**Results:** There were 23 patients in group A and 21 patients in group B who completed the study. Based on the CSI-4 assessment, AD scores decreased from the mean ( $\pm$ standard deviation) of 18.39 ( $\pm$ 5.44) to 15.39 ( $\pm$ 5.89),  $p=0.006$  in group A, whereas the mean AD scores for group B only changed from 15.0 ( $\pm$ 6.4) to 14.9 ( $\pm$ 5.94),  $p=0.55$  in group B. In addition, the mean of the HA scores decreased from 18.0 ( $\pm$ 6.73) to 13.3 ( $\pm$ 6.75),  $p=0.001$  in group A, whereas the change in HA scores in group B only diminished and from 11.85 ( $\pm$ 6.44) to 11.45 ( $\pm$ 5.44),  $p=0.74$ . The CSI-4 assessments and the scores on the Conners questionnaire significantly decreased after the first week of intervention ( $p=0.04$ ) in group A, but not in group B. No side effects were observed.

**Conclusion:** Subjects who received auricular therapy in acupuncture points achieved a statistically significant greater reduction in AD and HA symptoms when compared with subjects who received sham acupuncture points.

**Keywords:** acupuncture, attention deficit disorder with hyperactivity, clinical trial, complementary therapies

### Introduction

**A**TENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) is one of the most common neurodevelopmental psychiatric disorders starting in childhood. It has consequences

such as behavioral and disciplinary problems. It also can frequently be accompanied by substance abuse, antisocial behaviors, and high-risk sexual intercourse in adulthood.<sup>1</sup> Its prevalence in children is reported as occurring in 3% to 19% worldwide.<sup>2</sup> The prevalence of the disorder of ADHD ranged

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from 3% to 6% in 7- to 12-year-old children in Tehran<sup>3</sup> and 12.3% in Mashhad's kindergartens.<sup>4</sup> Prefrontal lobe dysfunction, and abnormal levels of neurotransmitters such as dopamine, noradrenaline, and serotonin have been suggested as neurophysiological factors that contribute to the etiology of ADHD.<sup>2</sup>

CNS Stimulants are highly effective in controlling the signs and symptoms of ADHD in 65% to 75% of patients, but 20% to 30% of patients with ADHD do not respond adequately to these medications, or they cannot tolerate their side effects. Stimulants can lead to exacerbation of tic behaviors, temporary growth retardation, heart palpitations, increased blood pressure, and disturbances in appetite and sleep.<sup>1,5</sup> Lack of the availability of this medication in Iran is another problem.

Acupuncture is one of the commonly used methods of complementary/alternative medicine.<sup>6</sup>

Ear acupuncture or auricular acupuncture is a modality of auricular therapy. It is a component of the body's micro-acupuncture systems that involves the stimulation of auricular acupoints that correspond to specific areas in the body.

This microsystem was first described by Dr. Paul Nogier, a physician in France who was also trained in acupuncture procedures. He discovered that the external ear represents all of the physical body, with correspondence to physiological and anatomical correspondences. Nogier further found that stimulation of these auricular points was intriguingly effective in alleviating pain and other symptoms in specific areas of the body.<sup>7,8</sup>

Although the exact mechanism of action has not been determined, multiple studies have shown the efficacy of ear acupuncture and auricular therapy for certain conditions.<sup>8</sup> Auricular acupuncture has been used for the relief of chronic neurological pain such as migraine, polyneuropathy and radiculopathy, irritable bowel syndrome, anxiety, obesity, smoking cessation, and abuse of alcohol and other substances.<sup>8-13</sup>

It has also been shown in functional magnetic resonance imaging that stimulation of specific points in the external ear activates certain areas of the brain. Moreover, auricular therapy has led to increases in the levels of the neurotransmitters such as enkephalin, metenkephalin,  $\beta$ -endorphin, and some hormones, such as adrenocorticotropic hormone and growth hormone.<sup>7,8</sup>

Due to the involvement of the dopamine system in hyperactivity (HA) and attention deficit (AD) disorder, ear acupuncture or auricular therapy may be an effective alternative treatment of ADHD.<sup>14-16</sup>

Farokhzadi and Khosli have already demonstrated the helpful effect of auricular therapy on attention in ADHD patients. However, their study lacked a control group, thus no precise conclusion can be drawn about the generalized effect of this method.<sup>17</sup>

Therefore, this study was conducted to evaluate the effect of auricular therapy on ADHD symptoms in 6- to 14-year-old children under welfare supervision in Tehran, Iran.

## Materials and Methods

This single-blind, randomized sham-controlled trial was conducted between 2018 and 2019 at four welfare centers in Tehran, Iran. The protocol was approved by the ethics committee of research of Iran University of Medical Sciences

(ethics code: IR.IUMS.REC.579) and registered at the Clinical Trials Registration Center of Iran (IRCT20090527001957N9).

The desired sample size was calculated to be 25 patients in each treatment group, considering a random error of 0.5 and power of 80%, with a standard deviation (SD) of 5 for the score of the two parts of the Children Symptom Inventory (CSI) questionnaire, AD and HA.

The participants were children aged 6-14 years who were diagnosed with ADHD according to DSM-5 criteria, their CSI-4 score, clinical judgment of a psychiatrist, and a family physician. Scores on the CSI-4 questionnaire scores for the AD section needed to exceed 6, and the HA section needed to exceed 5 to meet the inclusion criteria. If medication, education, and occupational and psychological therapies were used, there was no change in drug dosage or treatment or symptoms of ADHD for at least the past 2 weeks. The managers at the mentioned centers completed the written informed consent for each participating child.

Exclusion criteria were epilepsy, schizophrenia, hyperthyroidism, active psychotic or major mood disorder, intellectual disabilities, and autism spectrum disorder. Changes in medication type or dosage, changes in nonpharmacological therapies and severe worsening of symptoms during the study, lack of co-operation, and use of new therapies (compared with prestudy) during the study were considered as attrition criteria.

## Randomization

Patients were randomly assigned into two groups by using the block randomization method. Closed envelopes were utilized for random concealment that the individual number was on the envelope and the intervention type was inside it.

## Interventions

In group A, auricular therapy was performed at six ear acupoints, including the shen men point, point zero, hippocampus, prefrontal cortex, master oscillation point, and laterality point.<sup>7</sup> Active ear points were identified by a transcutaneous electrical device (point finder: POINTER EXCELL II T.E.N.S. plus; IND. CO., Hong Kong) looking for a change in electrical resistance or conductance at that point. The device has an output of 10 microamperes (mA) in detection mode, which is usually undetectable by the patient experiencing the procedure. Thus, the patient usually cannot tell whether electrical current is being activated or not on the active ear point or the sham ear point.

Then, the points were stimulated bilaterally (except for the laterality point) by a 2-mA DC pulse (with the same device).

The electrical stimulation was done by transcutaneous electrodes with a frequency of 10Hz and a duration of 20 sec at each point. The length of time that each individual was evaluated and received stimulation was 15 min.

These electric pulses were reported by the participants as painless and comfortable. Electrical stimulation was repeated once a week for 6 weeks. After stimulation, these ear points were labeled with small sections of adhesive tape that contained a small granule (Vaccaria seeds); then, the patients' supervisors were asked to apply medium pressure once a day for 1 min on each of the ear seeds. The acupuncture practitioner had >8 years' experience in this field,

and selection of these points was based on the therapeutic protocol of Dr. Terry Oleson and Dr. Beate Stritmatter.<sup>7,18</sup>

In group B, nonacupuncture points were selected in the control group, they were not electrically stimulated, and only the seedless adhesive tapes were attached.

Adhesive replacement was performed once a week for 6 weeks to allow the control and treatment groups to remain blind to the auricular therapy.

### Outcome measures

To assess the severity of ADHD, the 48-item parent's version of Conners Comprehensive Behavior Rating Scale and the 18-item CSI-4 were given to participants at baseline, 1 week, and 7 weeks after the sixth session of intervention. There are several different versions of the Conners questionnaire. In this study, the 48-item parent's version of Conners questionnaire was used, which contains 10 questions that examine HA. Other items examined by this questionnaire include conduct disorder, learning disorder, psychosomatic disorder, impulsive disorder, and anxiety. The severity of each symptom ranged from 0 to 3 (never, sometimes, often, most of the time). A higher score indicates greater severity of the disorder. Its validity and reliability have been well demonstrated in previous studies.<sup>19–23</sup>

The CSI-4 questionnaire examines disorders such as conduct disorder, anxiety, psychotic disorders, and several other disorders, but only 18 questions were used in this study, 9 of which were for AD and 9 for HA. The total score of questions 1 to 9 indicates the severity of AD, and the total score of questions 10 to 18 indicates the severity of HA. The severity of each symptom ranged from 0 to 3 (never, sometimes, often, most of the time). In both sections, higher scores indicate more behavioral disruption and lower scores signify improvement in ADHD symptoms. The reliability and validity of this CSI-4 questionnaire have been proven in multiple, previous studies.<sup>24–26</sup>

In addition, to evaluate the behavioral changes of patients, their instructors were asked about the change in ADHD symptoms of HA and AD and the instructors scored the changes as: no change, improved, or got worse. The primary outcome was the score of CSI-4 in the AD and HA sections. The secondary outcomes were the score of the Conners Questionnaire and qualitative assessment.

Data were analyzed by using SPSS17 software. Mean and SD were reported for quantitative data, as well as the number and percentage of qualitative data. The difference between the two groups was assessed by Mann–Whitney *U* test and within each group it was assessed by Friedman test. Chi-square test was used to compare the qualitative variables between the two groups. *p* Values <0.05 were considered statistically significant.

### Results

A total of 86 children were evaluated for inclusion and exclusion criteria. The 50 patients who were included in the study were then randomly assigned into two groups. By the completion of the study, 23 patients remained in the auricular therapy group and 21 in the sham group who completed all treatment parts of the study. Figure 1 shows the CONSORT flow diagram of this study. Loss of adhesive tapes and exacerbation of symptoms were the reasons for the attrition of patients.

The mean  $\pm$  SD of age was  $9.8 \pm 2$  years and it was statistically distributed identically between the two groups ( $p=0.77$ ). Of the total of 46 patients who completed the study, 36 (81.8%) of the participants were male and the gender distribution was identical between groups A and B ( $p=0.44$ ).

The scores of the CSI-4 questionnaire at different times of the study are shown in Table 1. Table 1 shows that the mean AD score in the auricular therapy group decreased significantly ( $p=0.007$ ,  $p=0.006$ ), but not in the sham, control group ( $p=0.46$ ,  $p=0.55$ ). The HA score in the group A also decreased significantly ( $p=0.001$ ,  $p=0.001$ ), but not in the control group ( $p=0.37$ ,  $p=0.74$ ).

Because of the significant difference in HA score between the two groups at the beginning of the study, and to eliminate its confounding effect, the degree of change in the AD and HA scores during the study was compared between groups. The values in the Table 1 indicate that the decrease in the AD and HA scores in the first week after the intervention was significantly higher in group A compared with the baseline values ( $p=0.04$ ,  $p=0.008$ ). In addition, the decrease in HA in the seventh week after the intervention was significantly higher in the auricular therapy group than in the sham control group ( $p=0.04$ ).

The HA scores calculated by the 10-item Conners questionnaire and its changes during the study are shown in Table 2. This table shows the significant effect of auricular therapy on HA symptoms.

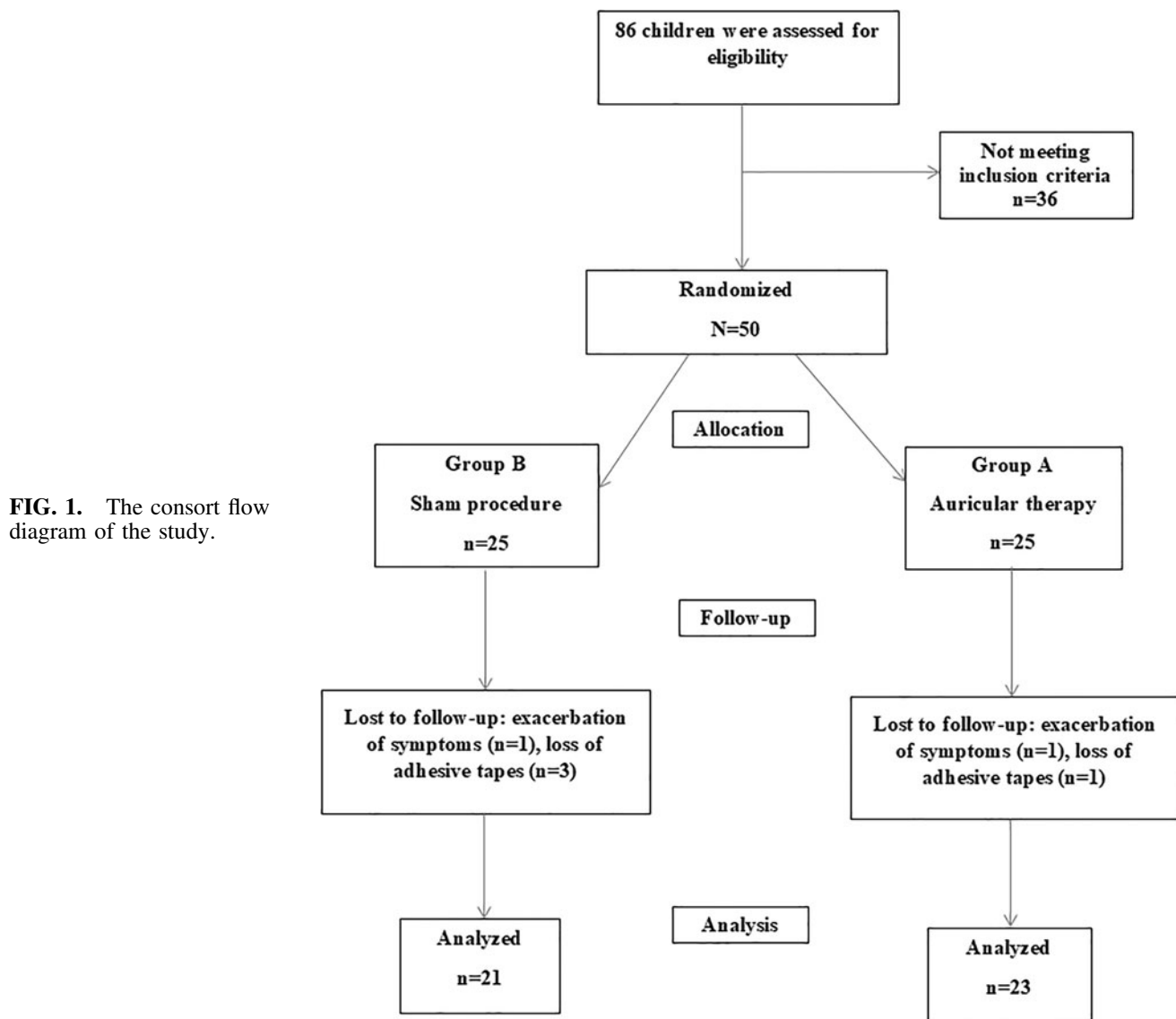
According to the Conners Questionnaire, some children have distinctive comorbidities. Table 3 shows the frequency of these comorbidities. According to Table 3, the frequency of comorbidities was similar in both groups except for impulsiveness, which was higher in the auricular therapy group. The mean  $\pm$  SD of changes of the AD score in the two groups, with or without impulsiveness, were  $2.5 \pm 5.45$  and  $2.6 \pm 3.54$  ( $p=0.38$ ), and the respective changes of the HA score were  $5.62 \pm 6.41$  and  $2.4 \pm 2.79$  ( $p=0.2$ ). This finding suggests that patients with or without impulsiveness responded equally to auricular therapy. In addition, there was no difference in the effect of auricular therapy compared with sham treatment on reducing the AD and HA symptoms in the group with the impulsive disorder ( $p=0.22$  and  $p=0.11$ ).

Evaluation of the instructor viewpoints about the changes in symptoms showed that in general, HA, impulsiveness, and anger were improved in 17 patients, of whom 14 were in group A (auricular therapy) and 3 were in group B (sham control). For 24 patients, there were no obvious changes in instructor evaluation of symptoms, 9 in group A and 15 in group B. There was an increase in the symptoms of one patient in group B. The chi-square test showed statistically significant differences between groups ( $p=0.005$ ).

### Discussion

The results of this study demonstrated that children with ADHD exhibited significantly greater improvement after receiving auricular therapy than did children in the sham control group, thus demonstrating a reduction in AD and HA symptoms in these children.

Ear acupuncture and auricular therapy are usually used interchangeably; however in auricular therapy, the acupuncture points are stimulated with pressure or electrical stimulation and acupuncture needles are not used.<sup>7,8,11</sup>



There are some articles about the effects of acupressure or “Transcutaneous Electrical Acupoint Stimulation” (TEAS) on some disorders,<sup>27,28</sup> however, a literature search did not reveal any articles about the effects of acupressure or TEAS on ADHD. We found one study that examined the efficacy of

the auricular therapy with mitigating ADHD symptoms.<sup>17</sup> It was published in 2019 and evaluated 7- to 14-year-old children with ADHD without any control groups. The CSI-4 and the integrated visual and auditory test were used for outcome evaluation. The auricular points stimulated included the brain

TABLE 1. CHILDREN SYMPTOM INVENTORY-4 SCORES AND CHANGES DURING THE STUDY

Time period	AD score			HA score		
	Auricular therapy	Sham control	p <sup>a</sup>	Auricular therapy	Sham control	p <sup>a</sup>
Mean (SD) at baseline	18.39 (5.44)	15 (6.4)	0.07	18 (6.73)	11.85 (6.44)	0.004
Mean (SD) on 1st week after intervention	15.82 (4.81)	14.85 (6.17)	0.57	14.47 (6.11)	12.95 (4.83)	0.47
<i>p</i> <sup>b</sup>	0.007	0.46		0.001	0.37	
Mean (SD) change from baseline to first week	2.65 (4.17)	0.14 (4.6)	0.04	3.52 (4.53)	-1.09 (5.59)	0.008
Mean (SD) on seventh week after intervention	15.39 (5.89)	14.9 (5.94)	0.8	13.3 (6.75)	11.45 (5.44)	0.28
<i>p</i> <sup>b</sup>	0.006	0.55		0.001	0.74	
Mean (SD) change from baseline to seventh week	3.00 (5.09)	0.09 (4.53)	0.13	4.69 (6.37)	0.7 (5.61)	0.04

<sup>a</sup>Comparison between groups by Mann–Whitney *U* test, negative value means increase.

<sup>b</sup>Comparison within group by Friedman test.

AD, attention deficit; SD, standard deviation; HA, hyperactivity.

TABLE 2. CONNER'S HYPERACTIVITY SCORES AND CHANGES DURING THE STUDY

Time	HA score	
	Auricular therapy	Sham control
Baseline, mean (SD)	19.17 (5.13)	14.61 (4.92)
First week after intervention, mean (SD)	16.11 (6.42)	12.63 (5.69)
<i>p</i> <sup>a</sup>	0.046	0.52
Seventh week after intervention, mean (SD)	16.55 (6)	14.05 (6.15)
<i>p</i> <sup>a</sup>	0.08	0.59

<sup>a</sup>Comparison within group by Friedman test. SD, standard deviation; HA, hyperactivity.

point, excitement point, prefrontal cortex point, shen men point, and tranquilizer point, which were subjected to moderate pressure without electrical stimulation, using only adhesive tapes. Results indicated that there was improvement on the auditory vigilance subscale and the auditory prudence subscale after 8 weeks of auricular therapy, whereas the CSI-4 score did not change significantly.<sup>17</sup>

There are studies conducted on the efficacy of acupuncture for ADHD. The Cochrane review in 2011 examined the effect of acupuncture on ADHD in children and adolescents and concluded that none of the studies met the inclusion criteria, suggesting the need for higher quality studies in this field.<sup>2</sup> A systematic review and meta-analysis in 2015 evaluated the efficacy of acupuncture on ADHD from 13 clinical trials and concluded that acupuncture is an effective way to treat the disorder and can be more even effective when combined with pharmacological or behavioral therapies. It has been recommended to conduct further high-quality studies. The full text of this 2015 paper was published in Chinese and we were not able to fully analyze it.<sup>29</sup>

In another review study published in 2011, out of 114 existing clinical trials, only 3 could be entered in the meta-analysis because of the high risk of bias in existing studies; thus, it was not possible to reach a final conclusion about the efficacy of this method for ADHD.<sup>30</sup>

There may be a deficiency in the dopaminergic system in individuals with ADHD.<sup>31</sup> From the Western neurophysiological perspective, auricular therapy may mitigate dysfunctions in prefrontal cortex activity.<sup>11</sup>

The neurochemical mechanism of acupuncture/auricular therapy in ADHD is not well understood, but there is one

TABLE 3. FREQUENCY OF COMORBIDITIES

Comorbidities	Group		<i>p</i> <sup>a</sup>
	Auricular therapy	Sham control	
Conduct disorder, <i>n</i> (%)	20 (66.7)	16 (76.2)	0.44
Learning disorder, <i>n</i> (%)	13 (56.5)	10 (47.6)	0.76
Impulsiveness, <i>n</i> (%)	8 (34.8)	1 (4.8)	0.02
Psychosomatic disorder, <i>n</i> (%)	2 (8.7)	0	0.48
Anxiety, <i>n</i> (%)	3 (13)	4 (19)	0.69

<sup>a</sup>Chi-square test.

hypothesis that acupuncture/auricular therapy leads to an improvement of dysfunctions in the mesolimbic-dopaminergic system, possibly activated by changes in the neurotransmitters such as serotonin, enkephalin, GABA, and dopamine. This system is known as the reward and pleasure systems of the brain. Disruption of this system has been shown to lead to impulsive behaviors, whereas improvement in this system is able to reduce impulsivity.<sup>14</sup>

The difference between the two groups in terms of impulsiveness at the beginning of the study could be a confounding factor, but the analysis for adjusting the confounder showed that patients with or without impulsiveness responded equally to auricular therapy. However, a conclusive finding is not evident due to the small sample size.

The reason for choosing the Iranian welfare centers for this study was that, according to previous research, the prevalence of ADHD was higher in these centers. Further, these welfare centers provided the possibility to randomize one group to the sham treatment at the same time as other patients were given the auricular therapy at acupoints. For patients referred to a private office or a medical center, it was not possible to meet patient's needs by randomizing them to a sham procedure. Further, in clinical studies conducted in an office or medical center, many participants could be lost to follow-up procedures, which could prolong the study duration and increase the costs.

The utilization of these mentioned centers did have some limitations. For example, some of these centers did not have the necessary cooperation with the project executives and there was some fear of providing patient information. Regarding the children and their symptoms, it seems that their particular lifestyle, living with other children in a busy and stressful environment, and lack of their parents can exacerbate the symptoms or decrease the effect of therapeutic interventions. However, this was an initial study and it is recommended to repeat it in other settings.

Trainers were instructed to exert moderate pressure on the points throughout the week, but the extent to which they took on that responsibility was unclear and may have been neglected.

Parents of the affected child are more likely to follow this request at home and thus the results could be better. In the welfare centers where some children and adolescents lived in overcrowded and busy settings, educators tended to focus on the HA and tended to focus on them calming them down. Therefore, HA questions have been answered more carefully.

One of the design limitations of this study was the small sample size. This study should be considered a pilot study. Further studies with larger sample sizes are necessary. Another issue was probable awareness of participants with regard to treatment procedures. Since one group did not get the electrical stimulation, it could be considered as an open label (without blinding) trial.

**Conclusion**

Auricular therapy was able to significantly reduce AD and HA symptoms in children with ADHD to a greater degree than was observed with a sham control treatment. Studies with a larger sample size, in other settings and with other control groups, are recommended.

### Author Disclosure Statement

No competing financial interests exist.

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