



Research paper

Efficacy of adding acupuncture to Methylphenidate in children and adolescents with attention deficit hyperactivity disorder: A randomized clinical trial



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ABSTRACT

Introduction: Attention deficit hyperactivity disorder (ADHD) is the most prevalent finding in children with behavioral issues. It has been shown that acupuncture, as a complementary medicine, may have some beneficial effects in ADHD treatment; however, the available evidence of its effectiveness are inadequate. This study aimed to investigate the effectiveness of acupuncture treatment in patients with ADHD.

Methods: This double blind randomized sham controlled trial was conducted on patients with confirmed ADHD referred to Ibn-e-Sina Psychiatric Hospital, Mashhad, Iran between January 2017 and June 2017. Patients were randomly allocated into either an acupuncture (experimental group) or a sham acupuncture (control group). All patients received a standard treatment of 0.3–1 mg/kg of Methylphenidate (Ritalin) in 2 or 3 divided doses. Within 4 weeks the intervention group received acupuncture treatment 3 times a week. Sham acupuncture was used for the control group within the same duration as acupuncture group. The treatment outcomes were measured using home version of ADHD-rating scale (RS) and the Continuous Performance Test after 3 weeks. Independent-samples *t*-test, Pearson Chi-square test, and Paired-samples *t*-test were used for data analysis with SPSS version 16.0.

Results: This study was conducted on 59 patients (52 males) with a mean age of 10.64 ± 2.46 years in two groups of experiment ($n = 31$) and control ($n = 28$). ADHD-RS total score was significantly more decreased in acupuncture group after 3 weeks (-6.29 ± 7.1 vs. -1.96 ± 6.7 ; $p = 0.007$). Also, the hyperactivity and impulsivity was significantly more decreased in the acupuncture group compared to the sham control group (-3.29 ± 3.7 vs. -0.45 ± 4.1 ; $p = 0.005$). Furthermore, acupuncture did not considerably change Omission error, Commission error, Reaction Time and Correct hit ($p > 0.05$).

Conclusion: Our study showed that acupuncture can significantly improve the parent-report ADHD-RS. Nevertheless, it did not improve the attention deficit. We recommend further investigations with larger sample sizes and longer follow-up. The adverse effects of acupuncture on ADHD patients were not assessed in this study, but should be measured in future studies.

1. Introduction

Attention deficit hyperactivity disorder (ADHD) is a condition characterized by hyperactivity, impulsivity and inattention [1]. These behaviors occur in 3–12% of children [2,3]. This condition is also

frequent in adulthood with the prevalence of 2.1–3.1% [4]. ADHD negatively interferes with various aspects of a child's life such as: social relationships, educational performance, and quality of life [5–7]. ADHD patients can be isolated from their peers due to aggressive behaviors [8]. Over time, ADHD patients experience lower educational

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achievements and job stability compared to the normal population [9,10]. Therefore, these effects will have negative economic impacts on the patients, relatives and society, which demonstrate the necessity for ADHD treatment.

Various studies have focused on ADHD treatment so far [11–14]. However, these findings have mostly addressed the pharmaceutical medication, while psychosocial interventions and complementary medicine are neglected [15,16]. Methylphenidate and dexamphetamine are widely used to improve behavioral, social and educational function of ADHD patients. But parents' refusal to use stimulants and concerns about side-effects such as: insomnia and irritability lead to a search for an alternative treatment [17–19].

The use of complementary medicine in ADHD is growing during recent years. It is estimated that 12–64% of parents applied complementary medicine for their ADHD children [20–22]. Acupuncture is a simple, cost-benefit and low-risk intervention, which is applied for therapeutic and prophylactic approaches [23]. Acupuncture is commonly recommended by family doctors as a complementary medical treatment [24,25]. Ancient Chinese medicine suggests that ADHD is due to inconsistency between Yin-Yang and heart, kidney and spleen disorders [26]. It should be noted that the organs' function in acupuncture is different from their physiological function. Acupuncture is now accepted as a medical intervention in western societies [27]; however, little evidence are available to endorse the beneficial effects of acupuncture for treating ADHD [28]. Although, several studies have failed to demonstrate any positive effect of acupuncture on ADHD symptoms [29,30], some other reports have shown that using additive electro-acupuncture treatment results more favorable outcomes compared to behavior therapy alone [31]. Also a recent meta-analysis has indicated limited evidence for the therapeutic effect of acupuncture for ADHD, and has recommended further investigations to confirm the effectiveness of acupuncture as a symptomatic treatment of ADHD [32].

The prevalence of ADHD is about 12.3% in Iran, which appears to be higher than many other countries [33]. Considering the high prevalence of ADHD in Iran, an inexpensive and a low risk treatment for ADHD seems essential. Acupuncture has been suggested to have beneficial effects on ADHD core symptoms; however, the use of acupuncture for the treatment of ADHD is still a matter of controversy. Moreover, according to the recently conducted systematic review, there are still significant gaps of knowledge on the topic of the effectiveness of ADHD nonpharmacologic treatments [34]. So the aim of this study is to investigate the effects of adding acupuncture to Methylphenidate on children and adolescents with ADHD.

2. Materials and methods

2.1. Study design and setting

This double blind randomized placebo controlled trial was conducted on ADHD patients referred to the Outpatient Child and Adolescent Psychiatric Clinic at Ibn-e-Sina Psychiatric Hospital, Mashhad, Iran between January 2017 and June 2017.

2.2. Participants

The inclusion criteria were as follows: (I) parents able to complete the written and oral informed consent (II) age between 6 to 18 years (III) diagnosis of ADHD according to DSM-5 criteria by a child and adolescent psychiatrist and (IV) being on the standard treatment with Methylphenidate or Methylphenidate and clonidine without any dose changes from 2 weeks before and during the study period. We excluded patients with mental retardation, epilepsy, pervasive developmental disorders, schizophrenia, manic episode, mood and anxiety disorders and drug or organic disorder induced hyperactivity. Also participants were excluded during the study period if any change happened in their standard fixed dose drug therapy.

2.3. Sample size

The sample size was calculated to be 45 subjects in each group. This sample size was calculated based on the results of previous studies [35]; considering a reduction of 30% of ADHD Rating Scale (RS) from 21 to 14.5 with a standard deviation of 9.5; by assuming the test power of 80% and a confidence level of 95%.

2.4. Allocation and blinding

Patients were randomized into two groups with a 1:1 allocation ratio including acupuncture (experimental group) or sham acupuncture (control group). Simple randomization was done by using a random number table. Randomization was done by a researcher who was not aware of the study protocol and outcomes. After being randomly allocated to the groups, patients were referred to the Acupuncture Clinic of Imam Reza Hospital, an academic hospitals affiliated to Mashhad University of Medical Sciences, Iran to get their acupuncture or their sham acupuncture. Patients and their parents, as well as child and adolescent psychiatrist were not aware of the grouping. None of the patients had previously experienced acupuncture, and as they were unfamiliar with needle sensation, both groups were blinded about whether they received verum or sham acupuncture. The psychologist, who was the researcher-in-charge of before-after tests, was not aware of which individual received which intervention. In addition, the researcher in charge of data collection was not the acupuncture physician, and was unaware whether patients received actual acupuncture or Sham acupuncture. Study outcomes were recorded by the psychiatrist who made no other contribution to the study.

2.5. Interventions

The experimental group was treated with acupuncture within 4 weeks and they had the overall of 12 sessions (3 sessions per week with 40 min duration). The Huan-Qui disposable acupuncture needles with tube were used and needles size were 0.25*25 mm (Fig. 1). First, the skin was sterilized by alcohol. The quick and perpendicular needle method was used for insertion; the tube was pulled out after the insertion. The needles were remained in the acupoints for 20 min with patient in the supine position and then 20 min in prone position. For the control group the sham acupuncture was used with different acupoints, which were close to the ones in the experimental group. The Asiamed placebo needles were used with tube, which were not actually inserted into the skin but made the patient feel the pressure similar to needle insertion. Other procedures were the same as mentioned for the experimental group. To reduce the risk of bias the sessions were scheduled in a way that patients of each group did not encounter each other. The principles of the acupuncture, including the points selection [36,37] and the inserting depth of each point [38,39] have been published in detail elsewhere. Briefly, for the experimental group we used 19

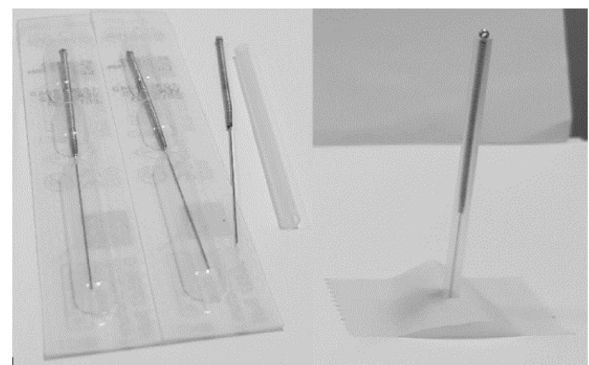


Fig. 1. The sham acupuncture needles used in this study.

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