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Research paper

Treating attention deficit hyperactivity disorder with acupuncture: A randomized controlled trial

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ABSTRACT

Introduction: Attention deficit hyperactivity disorder (ADHD) is the most common childhood behavioral problem. The purpose of this study was to evaluate the effectiveness and safety of acupuncture in patients with ADHD.

Methods: The study was randomized, waitlist-controlled, and unblinded. A total of 93 participants with ADHD were enrolled. The acupuncture group received acupuncture treatment twice per week for 6 weeks. The waitlist group did not receive acupuncture during the first six weeks, and then underwent acupuncture treatment during the next six weeks. The primary outcome measure was the ADHD-rating scale. The computerized neurocognitive function tests (CNTs) was conducted as an objective measurement.

Results: The results of the primary analyses were equivocal. Additional analyses were conducted after data were stratified according to ADHD medication. The acupuncture group not taking ADHD medications demonstrated significantly better performance in the CNTs compared to the waitlist group: the backward digit span test ($p = 0.026$), backward visual span test ($p = 0.044$), correct hit/omission error of auditory continuous performance test (CPT) ($p = 0.021$), standard deviation of response time of visual CPT ($p = 0.048$). The clinical global impression-severity score decreased significantly in the acupuncture group after treatment compared to that in the waitlist group ($p = 0.000$). There was no statistically significant difference between both groups taking ADHD medications, except for verbal learning test in which waitlist group experienced a higher increase than acupuncture group. No adverse effect was reported.

Conclusion: Acupuncture positively influences cognitive function in patients who are not on ADHD medication.

1. Introduction

Attention deficit hyperactivity disorder (ADHD) is not only the most common childhood behavioral problem, but also a frequent adult psychiatric disorder. A recent meta-analysis reported that the prevalence of ADHD in children, as defined by the Diagnostic and Statistical Manual of Mental Disorders fourth edition (DSM-IV), was 5.9–7.1% [1]. The defining features of ADHD include inattention, hyperactivity, and impulsivity [2]. Even though ADHD usually occurs in children, the prevalence of adult ADHD is not low, which is 2.1–3.1% [3]. In DSM-5, the definition of ADHD has been updated to more accurately characterize the disease in adults. This effort also ensures that some children with ADHD should continue to receive proper care throughout their lives. Given its long duration, it is important to identify the most effective and safe treatment for ADHD.

The literature on ADHD has grown rapidly over the last decade with more than 700 new publications in 2012 [4]. Most of these articles focus on the pharmacological therapies for ADHD. However, there is less emphasis on psychosocial interventions, and complementary and alternative medicine (CAM) [5–9]. Currently, stimulants such as methylphenidate are commonly prescribed as first-line treatments [8]. Stimulants have adverse effects including insomnia, anorexia, weight loss, depression, and anxiety [9]. Some patients are non-responders or suboptimal responders to stimulants. Furthermore, there is some uncertainty regarding the long-term safety of stimulant therapy. Therefore, parents and medical professionals alike are interested in exploring complementary and alternative treatments for ADHD.

Complementary and alternative therapies are commonly used for ADHD. Approximately 12–64% of parents with ADHD children have tried CAM therapies [10–12]. Acupuncture is one of the most

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popular CAM therapies. Its mechanism is unknown but it has many benefits that it is a relatively simple, inexpensive, and safe treatment compared to other conventional interventions [13].

Acupuncture is not currently recommended as a first-line intervention for ADHD due to a lack of clinical evidence regarding its use [14,15]. Several prior studies have reported that acupuncture eased the main symptoms of ADHD, but these studies have been criticized for their design. The process of randomization were inappropriate, or the participants were not randomized and were allocated arbitrarily [16,17]. The effectiveness of acupuncture was confounded by other interventions in some studies [18–26]. Therefore, the clinical utility of acupuncture in ADHD is still controversial.

We improved the methodological limitations of prior studies. We had designed the study in consideration of the appropriate randomization, reporting according to the Consolidated Standards of Reporting Trials (CONSORT) statement and the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA), and investigating the proper outcome measures for acupuncture effectiveness. The aims of this study are two-fold. First, we investigated the effectiveness of acupuncture in patients with ADHD (of any subtype) compared to waitlist controls. Second, we tried to assess the safety of acupuncture therapy in ADHD.

2. Methods

2.1. Design

The study was randomized, waitlist-controlled and unblinded. The study design consists of two parallel arms with a 1:1 allocation ratio. Preliminary plans were to enroll a total of 80 patients, but 96 patients were finally enrolled because of an uneven dropout rate.

The study protocol was approved by Kyung Hee Korean Medical Center Institutional Review Board (Seoul, Korea). The patients were informed about the purpose of the study, the data collection procedures, confidentiality, and their right to withdraw. Two types of informed consent forms were prepared: one for 7–13-year-old participants and the other for 14–18-year-old participants. We used a "comprehension check form" before allowing the 7–13-year-old participants to sign the consent form.

Subjects were recruited from July 2010 to January 2012. Newspaper and website advertisements were used to recruit patients. A total of 214 phone screenings were completed. Ninety-three eligible subjects were randomly allocated to one of two groups: acupuncture (group A) and waitlist (group W). Participants were stratified by the pharmacologic intervention at the initiation of the study. A computer-generated randomization scheme was used. The study protocol was registered at the Clinical Research Information Service (CRiS, KCT0000019).

2.2. Subjects

The study was performed at the outpatient neuropsychiatry department located in Kyung Hee University Korean Medical Center, Seoul, Korea. The subjects' parents were initially screened on the phone. Their children were included in the study if they met the inclusion criteria: (a) age between 7 and 18 years; (b) ADHD diagnosis (of any subtype) based on the DSM-IV criteria; (c) any intervention (pharmacological, psychosocial therapy, educational, occupational therapies etc.) without change in ADHD treatments/symptoms for last 2 weeks or no current treatment; and (d) informed verbal and written consent from parents and participants. Exclusion criteria were: (a) a diagnosis of mental retardation or pervasive developmental disorders; (b) past history of epilepsy or other neurotic disorder; (c) pregnancy; (d) any changes in medications during the course of the study. Any child who did not meet the inclusion criteria, or who met the exclusion criteria was excluded from the study.

2.3. Treatment

Every involved practitioner was a licensed doctor with a Medical Doctor of Korean medicine degree. Prior to the study, every practitioner received acupuncture safety education. The study protocol was previously published in July 2011 [27].

During each treatment visit, the participants were treated with 13 acupuncture points [Baihui (GV20)*1, Sishencong (EX-HN1)*4, Hegu (LI4)*2, Quchi (LI11)*2, Sanyinjiao (SP6)*2, Taichong (LR3)*2] [28]. The skin was first sterilized with alcohol. Thin, disposable acupuncture needles (stainless steel 0.20 mm diameter and 30 mm long; DONGBANG Acupuncture; www.dbneedle.com; Seoul, Korea) were then inserted approximately 3–10 mm (head: 3 mm; arms and legs: 5–10 mm) into the skin until the patient perceived the characteristic de qi without manual stimulation. Acupuncture needles were left in place for 20 min with the participant in the supine position. This identical treatment was conducted twice per week for 6 weeks.

The study was conducted with a semi-crossover design. The control group did not receive treatment during the first six weeks of the study. After the first six weeks, the participants in group W received the same acupuncture treatment as did those in group A. This study design was used not only for ethical purposes, but also for improving the analytic power. If any patient experienced worsening ADHD symptoms during the first six weeks of treatment, we excluded the patient from the study and gave acupuncture treatment in order to adhere to ethical standards.

2.4. Outcome assessment

The schedule of outcome assessment is shown in Fig. 1. The primary outcome for the study was change in ADHD symptoms from baseline to week 6 (or from week 6–12) as measured by the Korean version of the ADHD-rating scale (ADHD-RS) [29,30]. The ADHD-RS is a standardized, reliable 18-item assessment tool used in children and adolescents with ADHD. We used the additional parent rating scales as a secondary outcome measures including the Korean version of the Conners parent rating scale: short version (Conners-RS) and the Korean version of the IOWA-Conners rating scale: short version (IOWA-RS). The parent rating scales were measured at baseline and weeks 3, 6 and 9 (or 3, 6, 9, 12, and 15). Other secondary outcome measures include the Korean version of the Child Behavior Checklist (CBCL), the Clinical Global Impression-Severity rating scale (CGI-S), the Frankfurt Attention Inventory (FAIR), and the Computerized Neurocognitive function Test (CNT). The Korean version of the Child Behavior Checklist (CBCL) is also a parent rating scale, which is an empirically derived, highly valid, and reliable parent checklist in regard to pediatric psychopathology. It assesses several dimensions and is scored using established algorithms [31]. It has been proposed as a non-ideological method of characterizing comorbidity in individuals with ADHD [32,33]. We used the ADHD subscale and external subscale to measure ADHD symptom changes, in addition to total score. CBCL was measured at baseline and week 6 (or 6, 12).

The Clinical Global Impression rating scale (CGI) is a commonly used measure of symptom severity, treatment response, and treatment efficacy in patients with mental disorders [34,35]. We measured participants' ADHD symptom severity by the CGI-S. CGI-S was used at baseline and weeks 3 and 6 (or weeks 3, 6, 9, and 12). The CGI-improvement rating scale was used to assess dropout criteria. The Frankfurt Attention Inventory (FAIR), and the Computerized Neurocognitive function Test (CNT) were used to quantify the participants' cognitive impairments in ADHD. The