

CLINICAL STUDY

Comparison of clinical effectiveness of acupuncture and a Western drug on allergic rhinitis: study protocol for a randomized controlled trial

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be randomized to receive acupuncture or pharmacotherapy (1: 1) for 4 weeks with a 4-week follow-up. The primary outcome will be changes in 7-day average total nasal symptom score. Secondary outcome measures include rhinoconjunctivitis quality of life questionnaire score and total non-nasal symptom score.

RESULTS: The presence and seriousness of psychological and emotional impairments should be considered in therapeutic programs for allergic rhinitis. No clinical trial for treating allergic rhinitis via acupuncture regulation of psychological and emotional activities has been reported.

CONCLUSION: The findings of the trial will allow us to determine the effects of the mind (Shen)-regulation treatment approach. We will also be able to confirm if the effects of acupuncture are equivalent to those of the conventional drug cetirizine hydrochloride.

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Key words: Acupuncture; Rhinitis; Psychological and emotional impairment; Mind (Shen)-regulation; Randomized controlled trial

INTRODUCTION

Allergic rhinitis (AR) causes major illness and disability worldwide. Patients from all countries, all ethnic groups, and all ages suffer from AR.¹ The management of AR includes allergen avoidance, pharmacotherapy, immunotherapy, and surgery. Allergen avoidance and pharmacotherapy are first-line treatments for AR, but

Abstract

OBJECTIVE: To compare the efficacy of an acupuncture regimen for persistent allergic rhinitis (PER), aimed at improving a patient's mind or Shen in Traditional Chinese Medicine, to that of a second-generation H₁-receptor antagonist, cetirizine hydrochloride.

METHODS: This multicenter, randomized, controlled clinical trial on PER will be conducted at three institutions in China. The total study period will be 9 weeks. After a 1-week preparatory screening period, 240 eligible participants with PER will

recurrence of the disorder makes medication less effective over time. Although a new generation of medications with decreased side effects has been developed, side effects have not been completely eliminated.²

AR is called "Bi Qiu" (running nose) in Traditional Chinese Medicine (TCM) literature. Acupuncture has been used to treat AR since the first TCM classic, *Huang Di Nei Jing*.³ In recent years, clinical trials have been conducted to evaluate the efficacy of acupuncture for AR. Some trials showed that active acupuncture was more effective than sham acupuncture in decreasing the symptom scores for persistent allergic rhinitis (PER) and increasing the number of symptom-free days.^{4,5} In conjunction with routine care, acupuncture leads to clinically relevant and persistent benefits,⁶ is cost-effective according to international benchmarks,⁷ and has shown no serious adverse effects.⁴ However, because of experimental design weaknesses, such as lack of sham or placebo controls, lack of clear selection criteria, and inclusion of a mixture of different allergic rhinitis categories, the conclusions made by these trials are weak. Other problems in previous studies include insufficient details on acupuncture treatment procedures, particularly those related to rationales for acupoint selection and needling techniques.⁸ A systematic review of the clinical effectiveness of acupuncture for AR published in 2008 concluded that "there is currently insufficient evidence to support or refute the use of acupuncture in patients with AR. It is not possible to recommend acupuncture as a proven treatment for AR on the basis of published evidence."⁹ Consequently, 2010 Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines suggest clinicians not administer and patients not use acupuncture.¹⁰

However, trial design weakness and a lack of detailed descriptions of acupuncture treatment procedures could keep the modality from being recommended for AR. Better designed clinical acupuncture trials should be conducted, and reports of study results should conform to the Standards for Reporting Interventions in Clinical Trials of Acupuncture.¹¹ Additionally, new treatment protocols should be developed to improve acupuncture treatment effects so that choices besides pharmacotherapy can be offered to AR patients.

Psychological and emotional dysfunction and allergic rhinitis

Research reveals an interaction between psychological factors and allergic diseases. Allergic diseases can influence the psychological status of individuals to produce imbalances or other disturbances.^{12,13} Marshall *et al.*¹⁴ found that seasonal allergic rhinitis patients reported higher levels of general and mental but not physical fatigue, reduced motivation, and significant mood changes during ragweed season. A similar study also conducted by Marshall *et al.*¹⁵ showed that AR patients experienced subtly slowed cognitive processing speeds and some had difficulty with working memory during rag-

weed season. Kremer *et al.*¹⁶ reported that psychological wellbeing was significantly impaired in patients with symptomatic allergic rhinitis, as shown by higher scores in feelings of insufficiency, complaints of somatization, sleep disturbances, and depressive feelings. Leger *et al.*¹⁷ found that patients with moderate to severe symptoms of intermittent allergic rhinitis or PER suffered from impaired sleep, and all dimensions of sleep were involved. Bavbek *et al.*¹⁸ assessed the psychological status of AR patients and found statistically significant differences between patients and controls in all subscales of the Symptom Checklist-90 (SCL-90), particularly in somatization, depression, and general symptom index subscales. A study conducted in China also used SCL-90 to investigate the psychological status in AR patients and got a similar result.¹⁹ Sansone and Sansone²⁰ found that the majority of studies indicate associations between allergies and anxiety and mood syndromes in their review of PubMed and PsycINFO databases. For example, 97.1% of individuals in 10 of 12 studies on depressive syndromes expressed a positive relationship between allergy symptoms and some type of depressive syndrome. Moreover, 99.9% of individuals in nine of 11 studies on anxiety syndromes decisively expressed a positive relationship between allergy symptoms and anxiety syndromes.

On the other hand, allergic symptoms can be triggered and worsened by several psychological factors, including stress. Wright *et al.*²¹ suggested that psychological stress should be conceptualized as a social pollutant that can be "breathed" into the body to disrupt a number of physiological pathways, just as air pollutants and other physical toxicants can lead to increased risk of atopy. Stress might have independent effects in addition to its influence on atopy through its enhancement of neuroimmune responses to other environmental factors that operate through similar pathways. Nishioka *et al.*²² found that exposure to acute restraint stress inhibits antigen-specific antibody production in mice. This response suggests that acute stress has the potential to modulate the initiation of AR. A survey also showed that shy young adults had a higher frequency of hay fever than do extremely outgoing individuals.²³ Investigations into the personality traits of AR patients indicate a correlation between AR and poorer psychological functioning compared with control individuals.^{24,25} Kiecolt-Glaser *et al.*²⁶ observed the effects of stress and anxiety on immediate and late-phase skin test responses in AR and concluded that stress and anxiety can enhance and prolong AR symptoms.

Although the relationship between psychological factors and AR is recognized, few answers are available regarding whether regulating patient psychological and emotional state can improve the therapeutic effects of AR treatment.

Psychological factors and emotions are ascribed to mind, or Shen, in TCM. The aim of the current study is to assess the efficacy of an acupuncture regimen for AR that adds Shen-regulating points to the traditionally

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