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Original Research Article

Efficacy and safety of herbal steam bath in allergic rhinitis: a randomized controlled trial

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ABSTRACT

Background: Allergic rhinitis is a nasal mucosa inflammatory disorder that is induced by exposure to an allergen which results in four major symptoms, including anterior or posterior rhinorrhea, sneezing, nasal itching and nasal congestion. Allergic rhinitis may result in sleep disturbance, fatigue, depression of mood-cognitive function and quality of life impairment.
Objective: This study examined the efficacy and safety of herbal steam bath used for the reduction of allergic rhinitis symptoms, and evaluated treatment satisfaction and improvements in quality of life among participating patients with allergic rhinitis.
Design, setting, participants and intervention: A single-blind randomized controlled trial was conducted at Thai Traditional and Alternative Medicine Hospital between June and December 2016, using 64 subjects, equally divided into two groups. The treatment group received herbal steam bath and the control group received steam bath without herbs for 30 min 3 times a week for 4 consecutive weeks.
Main outcome measures: Allergic rhinitis symptoms, such as itchy nose, runny nose, sneezing, nasal congestion and watery eyes, were measured using the visual analog scale at weeks 0, 1, 2, 3 and 4. Quality of life was assessed at week 0 and week 4.
Results: The characteristics (sex, age, marital status, education, allergic rhinitis symptoms and frequency of symptoms) at the baseline were not statistically different ($P > 0.05$) between the two test groups. Anterior or posterior rhinorrhea symptoms, including sneezing, nasal itching and nasal congestion, were statistically reduced over the course of the treatment, but reductions were not significantly different between the control and treatment groups. The treatment group, however, was shown to be significantly more satisfied with the treatment than the control group ($P < 0.05$).
Conclusion: Both treatments appear to be able to significantly reduce the symptoms of allergic rhinitis. However, there was no difference in the effectiveness of steam bath with herbs and steam bath without herbs.
Trial registration: This trial was registered in the Thai Clinical Trial Registry with the identifier TCTR20170712002.

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1. Introduction

Allergic rhinitis is an inflammatory disorder of the nasal mucosa induced by exposure to allergens. The condition displays four major symptoms: anterior or posterior rhinorrhea, sneezing, nasal itching and nasal congestion. Allergic rhinitis symptoms result in sleep disturbance, fatigue, mood depression and a decrease in cognitive function, all of which impair quality of life [1]. The incidence of allergic rhinitis is a global health problem. Allergic respiratory diseases such as asthma and allergic rhinitis are increasing worldwide [2]. In Thailand, the incidence of allergies increases every year, and is predicted to increase 300–400 percent within the next 20 years. Currently, allergic rhinitis and sinusitis account for 23–50 percent of the incidence of allergies, for which most patients were treated symptomatically [3,4], including the use of antihistamines,

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nasal irrigation and nasal spray. Thai traditional clinical practice guidelines allow for the treatment of respiratory syndromes via methods such as herbal steam bath (HSB) for allergies [5]. HSB alleviated the effects of allergies well, but some patients are unable to benefit from steam bath (SB) because of allergies to the herbs. Patients who use SB without herbs still experience good results. However, there is no research on the efficacy of HSB and SB for relieving symptoms in patients with allergic rhinitis.

2. Materials and methods

2.1. Trial design

This study was a single-blind randomized controlled trial, in which the investigator was blinded.

2.2. Study setting

This study was conducted in the Outpatient of Thai Traditional and Alternative Medicine Hospital, Bangkok, Thailand. The study protocol was reviewed and approved by the Ethics Committee of the Traditional Thai and Alternative Medicine of the Department for the Development of Thai Traditional and Alternative Medicine, under the Ministry of Public Health, Thailand (approval number: RLC0041/59). It was registered in the Thai Clinical Trial Registry (trial registration identifier: TCTR20170712002).

2.3. Participants and intervention

The mean change between the baseline and the end of treatment was used as the main efficacy criterion. The mean difference between HSB group ($\mu 2$) and SB group ($\mu 1$) was assumed to be 0 (i.e., $\mu 2$ (test) $- \mu 1$ (control) = 0). The noninferiority margin (δ) was chosen to be 64 points and the standard deviation (σ) was estimated to be 90. By using the following formula for sample size calculation [6], setting α (significant level) = 0.05 and power at 80% ($\beta = 0.2$), Z value (standard score), n (sample size), μ (population mean), we estimated that 30 patients in each group would be the minimum. With a projected dropout rate of 15%, 34 patients per treatment group were needed.

$$n_1 = n_2 = \frac{2(z_\alpha + z_\beta)^2 \sigma^2}{(\mu_2 - \mu_1 - \sigma)^2}$$

One hundred and thirty subjects with allergic rhinitis, based on clinicians' diagnosis at the Thai Traditional and Alternative Medicine Hospital, were selected. The inclusion criteria were as follows: male or female, aged 20–65 years, having allergic rhinitis symptoms as described in the Allergic Rhinitis with its Impact on Asthma (ARIA) guidelines (i.e., patients experience itchy nose, runny nose, sneezing, nasal congestion and watery eyes more than 4 days per week) [7], and consent to participate in the research. The exclusion criteria were pregnancy, lactation, nose surgery up to four weeks prior to participation, fever of over 37.5 °C, dizziness, fatigue, insomnia, starvation, dermatitis, open wounds during the trial and a history of allergies to herbs, steam particles or heat.

Sixty-eight subjects fulfilled the inclusion criteria. They were randomized by a computer-generated list into two groups (34 persons each group). Allocation cards were placed in opaque, sealed and stapled envelopes by a nurse who did not participate in the research. The treatment group received HSBs and control group received SBs without herbs; baths were taken for 30 min three times a week (Monday, Wednesday and Friday) for 4 weeks. Both groups were assessed for symptoms of allergic rhinitis using the 10-mm visual analog scale (VAS; 0 = not at all bothersome, 10 = extremely bothersome) at weeks 0, 1, 2, 3 and 4. Quality of life was assessed at week 0 and week 4. Satisfaction with the treatment was assessed at week 4, as shown in Fig. 1. The herbs shown in Table 1 were steeped in water between 42 and 45 °C for use by the treatment group, but the control group used only water at the same temperature. The steam cabinet was made of pine wood and was 80 cm wide, 80 cm long and 180 cm tall. A thermostat controlled the internal temperature of the steam cabinet, and the chamber was protected by a ground fault interrupt circuit breaker. The two windows and the lamp inside the cabinet allow the health care provider to observe the patient during the treatment process. In case of an emergency, the patient can press a bell to alert the health care provider. Finally, the vent in the roof of the cabinet can be opened and closed and allows the health care provider to control how much steam is inside the cabinet. It was filled with steam and brought to the desired temperature before the patient entered (Fig. 2). Control and treatment baths were conducted in dedicated chambers to prevent exposure of the control group to the herbs.

All participants were informed about the research purposes and procedures. They signed informed consent forms and were assured that their information would be kept strictly confidential.

2.4. Outcome measures

Allergic rhinitis symptoms were measured in the subject using the 10-mm VAS for allergic rhinitis symptoms. A questionnaire was used to assess quality of life and satisfaction with the treatment. The questionnaires were from Clinical Practice Guideline of Thai Traditional Medicine [7]. All patients were asked to complete a set of questionnaires at baseline and after 4 weeks of treatment. Briefly, the questionnaires for quality of life contained 7 items

Table 1
List of herbal medicines in herbal steam bath.

Number	Scientific name	Part of use	Weight (g)
1	*Zingiber cassumunar*	Rhizome	75
2	*Curcuma longa*	Rhizome	75
3	*Kaempferia galanga* L	Rhizome	75
4	*Acorus calamus* L.	Rhizome	20
5	*Tamarindus indica*	Leaves	15
6	*Cinnamomum camphora* (L.) Presl.	–	2.5
7	*Dryobalanops aromatica* Gaertn.	–	2.5

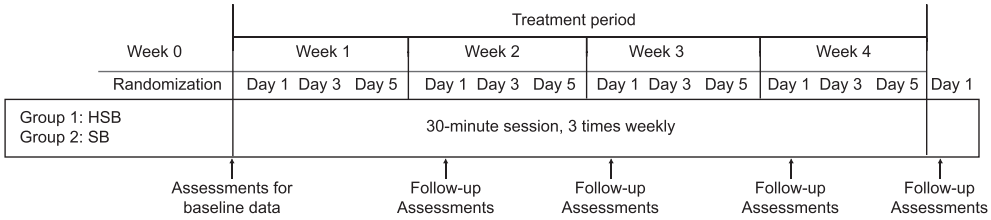

Fig. 1. Schedule of follow-up and assessment of participants HSB: herbal steam bath; SB: steam bath.