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BRIEF REPORT

TREATMENT FOR SEASONAL ALLERGIC RHINITIS BY CHINESE HERBAL MEDICINE: A RANDOMIZED PLACEBO CONTROLLED TRIAL

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Context • *Chinese herbal medicine (CHM) is widely used to treat seasonal allergic rhinitis (SAR), however, evidence of efficacy is lacking.*
Objective • *To evaluate the efficacy of a Chinese herbal formulation for the treatment of SAR.*
Design • *Randomized, double blind, placebo controlled trial.*
Setting • *RMIT Chinese Medicine Clinic.*
Patients • *55 patients with seasonal allergic rhinitis (active 28, placebo 27).*
Interventions • *CHM extract capsule (containing 18 herbs) or placebo, given daily for 8 weeks.*
Main Outcome Measures • *The primary measure of efficacy were changes in severity of nasal and non-nasal symptoms using a Five Point Scale (FPS) measured by both patients and the practitioner. The secondary measure was the change in score for the domains measured in the Rhinoconjunctivitis and Rhinitis Quality of Life Questionnaire (RQLQ) assessed by patients.*
Results • *Forty-nine patients completed the study (active 24, placebo 25). After eight weeks, the severity of nasal symptoms and non-nasal symptoms were significantly less in the active treatment group than in the control group, both for measurements made by patients and those by the practitioner. Comparison of active and placebo treatment groups RQLQ scores also indicated significant beneficial effects of treatment (end point Section 1: P<0.05; Section 2: P<0.01). Intention-to-treat analyses of categorical items showed moderate to marked improvement rates were 60.7% and 29.6% for active and placebo respectively. Eleven patients reported mild adverse events including 1 withdrawn from the trial.*
Conclusions • *This CHM formulation appears to offer symptomatic relief and improvement of quality of life for some patients with seasonal allergic rhinitis. (Altern Ther Health Med. 2003;9(5):80-87.)*

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Seasonal Allergic Rhinitis (SAR) is a common condition that significantly affects quality of life.[1] The prevalence rate of SAR varies between 1.4% to 39.7% of the population,[2] with relatively higher rates in western countries including Australia (10%).[3] Current western medical approaches for the management of SAR include drug therapy and immunotherapy. These therapies, however, are also associated with certain unwanted side effects, and in many cases, are unable to provide a complete relief of symptoms.[4] Therefore, alternative therapies have been used in the treatment of SAR[5] with a significant proportion of patients using Chinese herbal medicine.[6]

Chinese herbal medicine (CHM) has a long history in treating SAR in China. Several Chinese studies have suggested the potential usefulness of CHM in the management of SAR.[7-9] However, these studies are associated with certain methodological deficiencies, particularly in the lack of blinding and poor randomization, which may affect the validity of their findings.[10] Thus, there is inadequate scientific evidence available to substantiate the clinical use of CHM for the treatment of SAR. Accordingly, this study aimed to evaluate the effectiveness of a Chinese herbal formulation for the management of SAR using a randomized, double blind, placebo controlled clinical trial design.

METHODS

Patient Selection and Randomization

The trial was approved by the RMIT University Human Research Ethics Committee, and lodged with the Therapeutic Goods Administration, Commonwealth Department of Health and Aged Care, Canberra, Australia. Patients were recruited from the Chinese Medicine Clinic at RMIT University in Melbourne, Australia. After the completion of the screening questionnaire for

the purpose of initial selection, patients were invited for a personal interview, confirmation of western and Chinese medicine diagnosis, followed by treatment and assessment conducted at the same clinic. Randomization was conducted by an investigator not involved in the clinical part of the study. The randomization process was conducted by allocating a computer generated random number to all patients on the list and then sorting the list of patients by the assigned random number. The top/bottom 50% were then allocated to the treatment/control group. All patients were informed that there was a 50% chance of receiving placebo treatment. Patients were also advised that if they were allocated to the placebo treatment group, they would be offered the same amount of the active treatment in the following SAR season if the active treatment showed positive results. The inclusion and exclusion criteria are shown in Table 1. The assessment for each patient was conducted by the same ENT specialist (for severity of nasal and non-nasal symptoms assessment). The timing of the trial was based on previous studies on pollen counts and the pollen calendar.[11] The experimental phase of this study was conducted between July and December of 1999, with recruitment conducted from July to September and data collected between October and December 1999.

Herbal Preparation and Treatment Schedule

The active Chinese herbal formulation contained 18 different herbs (Table 2). They were selected on the basis of traditional use in Chinese herbal medicine for SAR. All herbs were produced in granule form and encapsulated. The granules of the herbal extracts were manufactured by a Good Manufacturing Practice (GMP) certified herbal pharmaceutical company in Taiwan (Min Tong Pharmaceutical Company). The granules were encapsulated by New Product Development (NPD) Pty Ltd in Queensland, Australia. The treatment codes of all herbal substances selected for this study were listed in the Australian Register of Therapeutic Goods and thus have been approved as suitable for human consumption. They were administered within the recommended dosages. All of the substances used are readily available throughout Australia. No animal products, endangered species and restricted herbal ingredients were used in this study.

The placebo capsules (matched for size, color, appearance and containing 500 mg of Soy polysaccharides) were also prepared by NPD.

All patients firstly entered a 2-week baseline period after initial assessment. The patients then were randomized and received either the active or placebo treatment (4 capsules each time, 3 times daily) for 8 weeks. The patient treatment code was strictly masked throughout the trial and data analysis period.

Outcomes

The primary endpoint with respect to efficacy was changes in severity of nasal and non-nasal symptoms, using a Five Point Scale, measured by both patients and the ENT specialist. The secondary endpoint was the change in score for the domains measured in the Rhinoconjunctivitis and Rhinitis Quality of Life Questionnaire (RQLQ) assessed by patients. Additional outcome measures employed including overall individual response to treatment, relief medication score, leftover capsule count, side effect record, patient opinion on CHM and blood tests.

FPS for the assessment of the severity of symptoms

The following Five Point Scale (FPS) was used for self-assessment of the severity of symptoms of SAR by patients and assess-

TABLE 1 Inclusion and Exclusion Criteria

Inclusion criteria

a. Age, 18-70 inclusive;
b. A history of typical symptoms of SAR including watery rhinorrhoea, sneezing, nasal congestion, nose itch and itching eyes for at least the last 2 to 3 years;
c. A positive skin prick test (SPT) to grass pollens; and
d. Provision of the written informed consent.

Exclusion criteria

a. HIV;
b. Previous history of specific immunotherapy (SIT);
b. Other active respiratory diseases such as asthma;
d. Nasal polyposis;
e. Systematic corticosteroid therapy;
f. Currently pregnant;
g. Hepatitis B and C.

TABLE 2 Capsule ingredients of the formula*

Chinese Name	Pharmaceutical Name	Concentrated Granule %
Dang Gui	Angelicae Sinensis, radix	3.81
Xi Xin	Asari, herba	2.25
Huang Qi	Astragali, radix	13.87
Bai Zhu	Atractylodis macrocephalae, rhizoma	7.11
Chai Hu	Bupleuri, radix	3.81
Sheng Ma	Cimicifugae, rhizoma	4.68
Dang Shen	Codonopsis pilosulae, radix	14.21
Gan Cao	Glycyrrhizae, radix	9.36
Chuan Xiong	Chuanxiong, rhizoma	4.68
Xin Yi	Magnoliae, flos	4.68
Bo He	Menthae, herba	3.81
Chen Pi	Citri reticulatae, pericappium	2.25
Che Qian Zi	Plantaginis, semen	4.68
Wu Wei Zi	Schisandrae, fructus	4.51
Jing Jie	Schizonepetae, herba	4.68
Fang Feng	Saposhnikoviae, radix	4.68
He Zi	Chebulae, fructus	4.68
Cang Er Zi	Xanthii, fructus	2.25

* Pharmaceutical terminology from PPC.[27]

ment by an ENT specialist: 0 = No symptoms; 1 = Very slight symptoms but noticeable; 2 = Moderate severity of symptoms; 3 = Severe symptoms; 4 = Very severe symptoms, as described by Prenner et al (1996).[12] Patients were asked to complete a study diary, scoring nasal symptoms (sneezing, rhinorrhoea, nasal congestion and nasal itch) and non-nasal symptoms (itching, watering, or redness of eyes and itchy ears / palate). They were also required to attend the clinic on fortnightly basis to be evaluated by an ENT specialist.

Rhinoconjunctivitis and Rhinitis Quality of Life Questionnaire (RQLQ)

All patients were required to complete a validated RQLQ fortnightly. The details of the questionnaire have been described elsewhere.[1]

Overall individual response to treatment

Overall individual response to treatment was rated by using the following seven-point scale (0 indicated no change, 1 to 3 indicated mild, moderate or marked improvement respectively whilst -1 to -3 indicated mild, moderate or significant worsening respectively).

Relief medication score

The Relief medication score questionnaire was completed throughout the study by each patient, identifying other medication used, the date and time of dosage, dose and effects of these drugs. The usage of medications was scored, based on daily dose and the following criteria: nasal spray/eye drop =1 point; short and long acting antihistamines=2 points; and, prescription only medications such as steroid nasal sprays = 3 points.

Leftover capsule count

Leftover capsule count was conducted throughout the study to monitor patients' compliance. The leftover capsule count counting was conducted by a blinded research assistant fortnightly when the bottles were returned to the clinic throughout the treatment period.

Side effects record

A side effect record form was handed out to all patients to record any unexpected signs, symptoms, and feelings during the treatment period. Details of any adverse events were scored using a six-point scale (0 = None; 1 = Minimal; 2 = Mild; 3 = Moderate; 4 = Severe; and 5 = Extremely severe) to indicate the severity of these events.

Patient opinion on CHM

Patients' opinion on Chinese herbal medicine was monitored by employing a validated instrument described elsewhere.[13] This was completed by all patients at the beginning and the completion of the study.

Blood tests

A full blood examination and specific and total immunoglobulin tests of IgE as well as IgG, IgA and IgM were conducted at the beginning and end of the trial by independent pathological test centers in Melbourne. Radioallergosorbent Tests (RASTs) were performed as described by Nalebuff and Fadal (1979)[14] Test results were scored between zero and 6 where a zero reading indicates no antibodies detected and 6 signifies the highest level of antibodies detected. Besides the Specific IgE for Couch/ Bermuda grass, Perennial Rye grass, Common Ragweed, Plantain/ Ribwort, Common Silver Birch and Cypress tree pollens, serum IgG, IgA and IgM were also measured.

Grass pollen counts were obtained from areas in which the patients resided, metropolitan Melbourne.[11]

Statistical analysis

All data were processed and analyzed by the Department of Statistics and Operation Research at RMIT University. Data were summarized as means and standard deviations (SD). There were no reliable data that could be used to precisely predict the effect size between the real and placebo treatment groups. If it is assumed that the placebo response might be as much as a 30% reduction of symptom severity, then for a 40% real reduction in symptom severity, there will need to be a reduction of 70% for the active treatment group. Therefore, the sample size of 28 patients per group provided for 80% statistical power to detect a 20% difference between the active and placebo groups at the a=0.05 level for the primary outcome measures.

Intention to treat analysis included all randomized patients who had baseline data and at least one follow up outcome after interventions were given. In addition, for categorical items, patients who withdrew from the study were recorded as having worsened. The data were analyzed using the Statistical Package for the Social Sciences (SPSS, windows Version 8) for Windows. The statistical procedure used was repeated measures analysis of variance utilizing the General Linear Model (GLM). The data from non-repeated measures were analyzed by *t-tests*. Outcome measures with categorical responses were analyzed using χ^2 and Fisher exact tests. All P values were 2-tailed and at α=0.05.

RESULTS

Demographic data and flow through study

Fifty-five adult patients were enrolled in the trial. Twenty-eight received active CHM capsules and 27 received placebo treatment. Six patients discontinued their participation prior to the end of the first 2 weeks of treatment, of which 5 lost to follow-up and one due to a skin reaction (Figure 1).

There were no statistically significant differences between the treatment and placebo groups in demographic data with respect to gender composition, baseline disease characteristics in relation to duration of SAR, family history of allergy, and the baseline Mean Total Symptom Scores (P>0.05). However, the average age of the patients in the active treatment group (43.5 ± 11.5 years old) was significantly higher (P<0.01) than that of the placebo group (34.6 ± 9.7 years old) (Table 3). Therefore, age was treated as a covariate when analyses of efficacy were performed.

Symptom score

FPS Baseline data

There was no significant difference between the active and placebo groups in the baseline data of nasal and non-nasal symptoms evaluated by either patient or the ENT specialist ($P>0.05$, Table 3).

Two week average nasal and non-nasal FPS symptom scores by patient

There was no statistically significant difference between the active and placebo groups in two week average nasal symptom scores during the periods of day 1-14 (run in period), 15-28 (treatment weeks 1 and 2) and 29-42 (treatment weeks 3 and 4) ($P>0.05$, Figure 2) or in the two week average non-nasal symptom scores during the periods of day 1-14, 15-28, 29-42, and 43-56 ($P>0.05$, Figure 2), recorded on a daily basis by patients. However, the

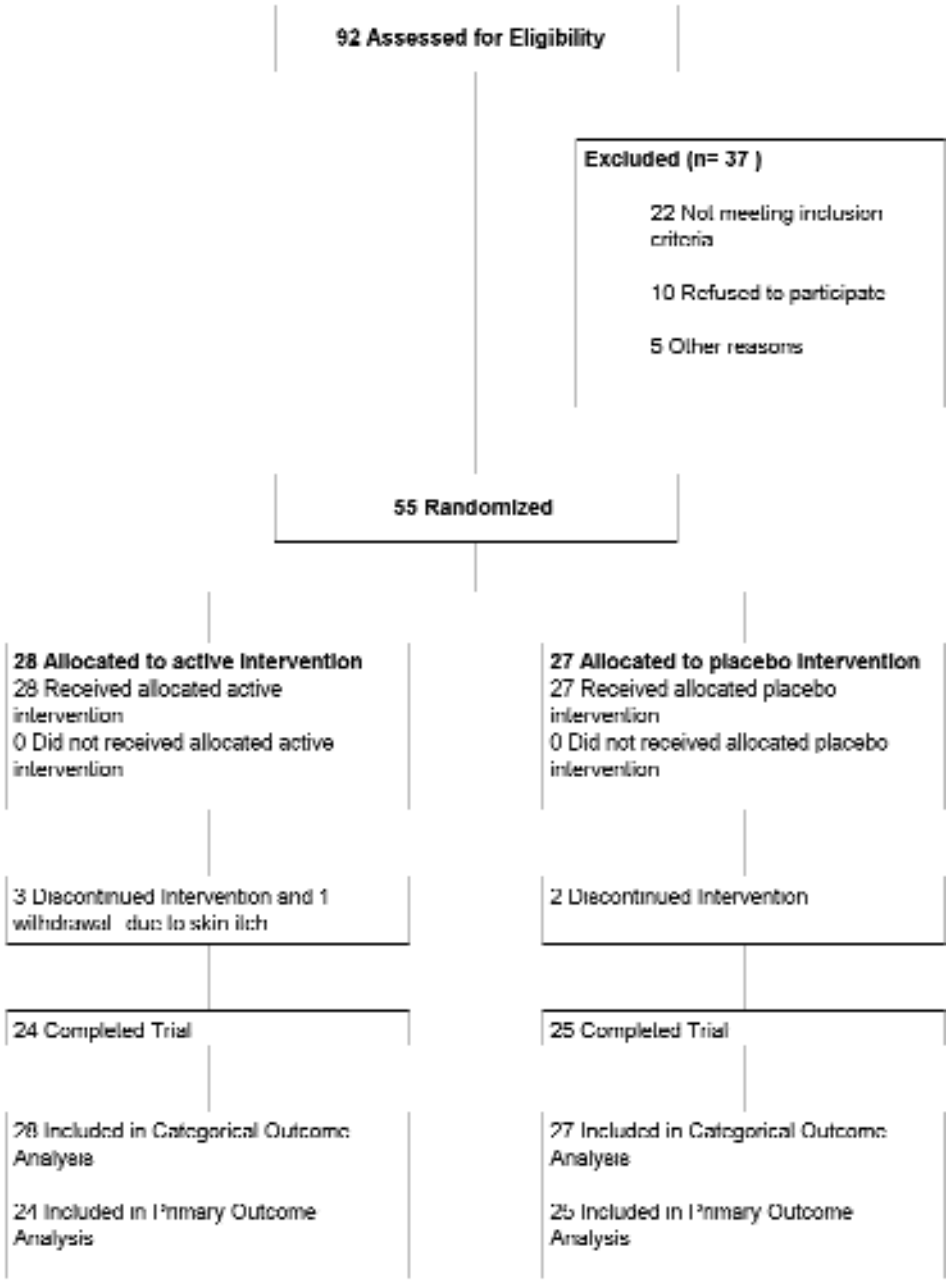

FIGURE 1 Patient progress through stages of the trial

active group showed a significantly lower average symptom score than the placebo group for both nasal symptoms during day 43-56 (treatment weeks 5 and 6) ($P< 0.05$) and day 57-70 (treatment weeks 7 and 8) ($P<0.01$) (Figure 2) and for non-nasal symptoms during day 57-70 ($P<0.05$) (Figure 2). The grass pollen count increased progressively from day 15–28 to day 43-56 (Figure 2).

Fortnightly average FPS symptom score by patient

There was no significant difference between the active and placebo groups in average nasal symptom scores on day 14, 28 and 42 ($P>0.05$) and non-nasal symptom scores on day 14, 28, 42, and 56 ($P>0.05$), recorded on a fortnightly basis when patients attended the clinic (results not shown). However, the active group showed a significantly lower score than the placebo group on nasal symptoms at day 56 and day 70 ($P<0.01$) and on non-nasal symptoms at day 70 ($P<0.01$) (the end point data on day 70 were shown in Table 3).

TABLE 3 Patient Population Characteristics before and after treatment: Nasal and Non-nasal Symptom Scores

Variables	Group: Active (*n* = 28) Mean (SD)	Group: Placebo (*n* = 27) Mean (SD)	*p* values
Characteristics			
Age, y	43.5 (11.55)	34.6 (9.7)	<0.01
Sex ratio (male : female)	1.15	0.47	>0.10
Duration of SAR	20.2 (13.3)	16.1 (8.9)	>0.10
Family history of SAR ratio (yes : no)	2.375	4.4	>0.10 >0.10
Mean total nasal & non-nasal symptom scores	16.0 (4.5)	15.5 (6.0)	
Baseline data			
Nasal symptoms by patient (per symptom)	2.29 (0.65)	2.34 (0.79)	>0.50
Non-nasal symptoms by patient (per symptom)	1.72 (0.73)	1.62 (0.89)	>0.50
Nasal symptoms by ENT specialist (per symptom)	2.08 (0.52)	2.07 (0.65)	>0.50
Non-nasal symptoms by ENT specialist (per symptom)	1.14 (0.73)	1.09 (0.80)	>0.50
RQLQ section 1 score	3.14 (1.20)	3.28 (1.08)	>0.50
RQLQ section 2 score	2.90 (1.51)	3.30 (1.15)	>0.50
End of treatment data			
Nasal symptoms by patient (per symptom)	0.84 (0.67) (n = 24)	1.43 (0.76) (n = 25)	<0.01
Non-nasal symptoms by patient (per symptom)	0.43 (0.59) (n = 24)	0.71 (0.69) (n = 25)	<0.01
Nasal symptoms by ENT specialist (per symptom)	0.79 (0.73) (n = 24)	1.39 (0.76) (n = 25)	<0.01
Non-nasal symptoms by ENT specialist (per symptom)	0.39 (0.57) (n = 24)	0.69 (0.68) (n = 25)	<0.05
RQLQ section 1 score	0.84 (0.87) (n = 24)	1.50 (1.04) (n = 25)	<0.05
RQLQ section 2 score	5.25 (0.98) (n = 24)	4.25 (1.49) (n = 25)	<0.01

Fortnightly average FPS symptom score by ENT specialist

No significant difference was observed between the active and placebo groups in average nasal symptom scores on day14, 28 and 42 ($P>0.05$) and non-nasal symptom scores on day 14, 28, 42, and 56 ($P>0.05$), recorded by the ENT specialist on a fortnightly basis when patients attended the clinic (results not shown). However, the active group showed a significantly lower score than that of the placebo group on nasal symptom scores on day 56 and day 70 ($P<0.01$) and on non-nasal symptom scores on day 70 ($P<0.05$) (The end point data on day 70 were shown in Table 3).

Rhinoconjunctivitis and Rhinitis Quality of Life Questionnaire

The RQLQ questionnaire comprises 2 sections. Section 1 included relevant symptoms and activities related to SAR. Section 2 recorded the impact of SAR on emotional aspects. There was no significant difference in the fortnightly average RQLQ scores (on both Section 1 and 2) between the active and placebo groups during trial period on day 0, 14, 28 and 42 ($P>0.05$, results not shown) but there were significant differences between the groups on day 56 and day 70 ($P<0.05$ for Section One scores; and $P<0.01$ for Section Two scores) (The baseline and end point data were shown in Table 3).

Overall individual response to treatment

Overall individual response to treatment is shown in Table 4. There was a significant difference between the active and placebo groups in SAR symptoms (Pearson's Chi-square test, $P<0.05$).

Other Scores

Relief medication score and Leftover capsule count

No significant differences were observed in the relief medication scores (End point: Active Treatment Group, 1.3±3.1; Placebo Group, 4.4±10.2) and the average two-week leftover capsule counts (End Point: Active Treatment Group, 12.5±25.6; Placebo Group, 21.6±27.7) during the trial period ($P>0.05$).

Patients' opinion on CHM

No statistically significant difference was observed between the active and placebo groups on the patients' opinion on CHM in relation to confidence, logicality, recommendation of CHM to others and confidence in CHM for other clinical conditions at Day 0 (Active Treatment Group: 73.1±21.4; Placebo Group: 72.6±18.2) and Day 70 (Active Treatment Group: 72.5±20.6; Placebo Group: 67.0±20.7) ($P>0.05$).

Adverse events scores: Safety

Approximately 21% of patients in the active group (6 out of 28) and 19% in the placebo group (5 out of 27) experienced mild side

effects. Five from the active treatment group and four from the placebo treatment group experienced bloating, indigestion and mild stomachache. These mild gastrointestinal side effects were tolerable and did not require additional treatment, as they resolved spontaneously. One patient from the placebo group who reported a dry nose also had similar symptoms prior to participating in the trial. No specific treatment was required for the management of this symptom. In addition, one patient (later confirmed in the active group) experienced a skin rash and leg edema, which were considered to be severe by the patient and medical attention was sought. This patient subsequently withdrew from the trial within the first two-week of treatment.

Laboratory results

No significant differences in both the average total IgE and specific IgE levels for Cypress, Birch, Plantain, Ragweed, Rye and Bermuda were observed between the active and placebo groups at Baseline (Day 0) and at end point (Day 70) ($P>0.05$) (Data not shown). Similarly, no significant difference between the two groups with respect to IgG, IgM, IgA levels and eosinophil and basophil counts were observed ($P>0.05$). (Data not shown.)

DISCUSSION

The present study has adopted strict blinding and randomization procedures to overcome the methodological deficiencies of previous studies employing CHM for allergic rhinitis.[7-9] In particular, we used well-defined inclusion and exclusion criteria[15] and independent assessments by patients and an ENT specialist. The patients included in the trial demonstrated homogeneity in relation to gender, duration of SAR and severity of the condition; although there was a small significant difference in age between the active and placebo groups. It has been suggested that age may play a role in SAR in that symptoms decline with age.[16] However, this was not supported by the present study. Nevertheless, we treated age as a covariate in our statistical analysis in order to minimize the impact of this factor on the outcome measures between the groups. All the outcome measures used in this trial have been previously validated.[1,12,17] A credibility scale was also incorporated into this trial to monitor the patients' opinion of the treatment they received for their SAR.[13,18] The similar levels of compliance with herbal medicine and patients' opinion on CHM through the trial indicate the blinding procedure was successful. Thus, the psychological influence is minimal in the outcome measures for this study.

As far as we are aware, this is the first double blind placebo controlled clinical trial using a strict and well-accepted methodological protocol to test the efficacy of a CHM formula in the treatment of SAR. The finding that the patients who received active CHM showed a statistically better outcome in relief of both nasal and non-nasal SAR symptoms compared to placebo suggests that the CHM formulation is effective in the clinical management of SAR. This finding is strengthened by the consistency of results from patient and an ENT specialist FPS scores, the RQLQ scores and the overall response rating with less treatment failure and no deterioration. However, these findings should be interpreted with caution taking the relatively small sample size into account. Larger trial is warranted to confirm the clinical efficacy of this CHM formulation in the treatment of SAR.

The immunological mechanism of SAR involves specific IgE mediated activation of mast cells, and release of inflammatory mediators on exposure to allergen (ie, pollen).[4] These inflammatory mediators, of which the most important is histamine, have immediate effects on target organs such as the eyes and nose to produce the characteristic acute symptoms and signs of SAR.[4] In addition, cytokines released by mast cells recruit other inflammatory cells, particularly eosinophils and T lymphocytes, which lead to the chronic allergic inflammatory response and produce chronic symptoms.[19] There is a slow onset of action of the CHM preparation in providing symptomatic benefit for this study. This suggests that the effect of the CHM preparation is not to prevent release of histamine, or inhibit its effect on target organs. There is evidence that CHM preparations may modulate cytokine production/release, particularly the TH2 profile, eg, IL4, IL5 and IL13 which are known to be involved in the allergic response.[20] Li et al (2000)[20] also reported that there was a slight but non significant reduction in total IgE in a mouse asthma model, and suggested an anti-inflammatory effect of CHM with reduction of eosinophilia and airway hyperresponsiveness may be involved. This is consistent with the present finding of the lack of effect of CHM formula on IgE levels over this short duration of therapy, indicating that a down-regulation of IgE synthesis is not the primary mechanism of action of the CHM. Therefore, the efficacy of the CHM tested may be due to slower onset anti-inflammatory actions, possibly modulation of cytokines and allergic inflammatory cells, by the various herbs used.[22-23] In addition, it is not clear whether the herbal formulation possesses a preventive effect, therefore, further studies are needed to elucidate the exact mechanisms of action of the CHM.

The overall tolerability of the herbal formulation is good although there were certain side effects reported with the trial, most commonly being bloating and indigestion. Five out of 28 patients in

TABLE 4 Patient rating of overall response to treatment

	Group, No. (%)		
Compared with before trial	Active treatment group (n=28)	Placebo group (n=27)	P values
Significant improvement	11 (39.3)	1 (3.7)	<0.05
Moderate improvement	6 (21.4)	7 (25.9)	
Mild improvement	3 (10.7)	5 (18.5)	
No change	3 (10.7)	4 (14.8)	
Mild worsening	1 (3.6)	5 (18.5)	
Moderate worsening	0	2 (7.4)	
Significant worsening	4 (14.3)	3 (11.1)	

the active treatment group and 5 out of 27 patients in the placebo group reported this unexpected discomfort. This gastrointestinal discomfort was reported mainly at the beginning of the trial and the degree of discomfort reduced after 2 weeks of intake. Since there was no difference in the probability of experiencing the discomfort between the active and placebo groups, it is difficult to establish the connection between these side effects and the active CHM capsules. The gastrointestinal discomfort may relate to the consumption of a relatively large number of capsules as the patients also commonly mentioned they did not expect to take 12 capsules per day. However, certain herbal medicine ingredients used (*Chai Hu, Sheng Ma, Chuan Xiong, Wu Wei Zi and Cang Er Zi)* may have the potential to produce gastrointestinal discomfort.[21,22] One patient from the active treatment group withdrew from the trial due to a skin rash and leg edema which needed medical attention. The patient was followed up for four weeks, on a weekly basis, and recovered completely with the aid of antihistamines. It is worth mentioning that the formula studied does not contain *Ma Huang*, a source of ephedrine and has been reported to be associated with central nervous system as well cardiovascular side effects.[22] Since the overall frequency of side effects were almost the same between the two groups, it is reasonable to suggest that the CHM formulation used in this trial is safe for SAR patients within the period of 8 weeks.

It should be pointed out that the dosages of all ingredients used for this trial were within the recommended range.[24] Public awareness of potential side effects due to overdosing and long term use of Chinese herbal medicine is often lacking.[21,22,24] In addition, we have no data on efficacy and tolerability of extended use (more than 8 weeks) with the Chinese herbal formulation. However, as SAR is a seasonal condition and therefore, the treatment for this condition is normally relatively short being restricted to the short period of peak pollen season.

In conclusion, this randomized, double blinded, placebo controlled trial demonstrates that the CHM formulation studied offers symptomatic relief of nasal and non-nasal SAR symptoms, the benefits being supported by both patients and an ENT specialist. The CHM formulation is well tolerated in comparison with the placebo group. However, there are no safety data available for more than eight weeks. Thus, we propose that, based on these data, this Chinese herbal medicine formulation should be considered as an option for symptomatic relief of some patients with SAR. However, these findings should be interpreted cautiously with consideration of the relatively small sample size. Furthermore, the exact mechanisms of action of this CHM are not clear, although it is consistent with a slow onset anti-inflammatory action. Further research is required to elucidate the exact mechanisms of action of this CHM.

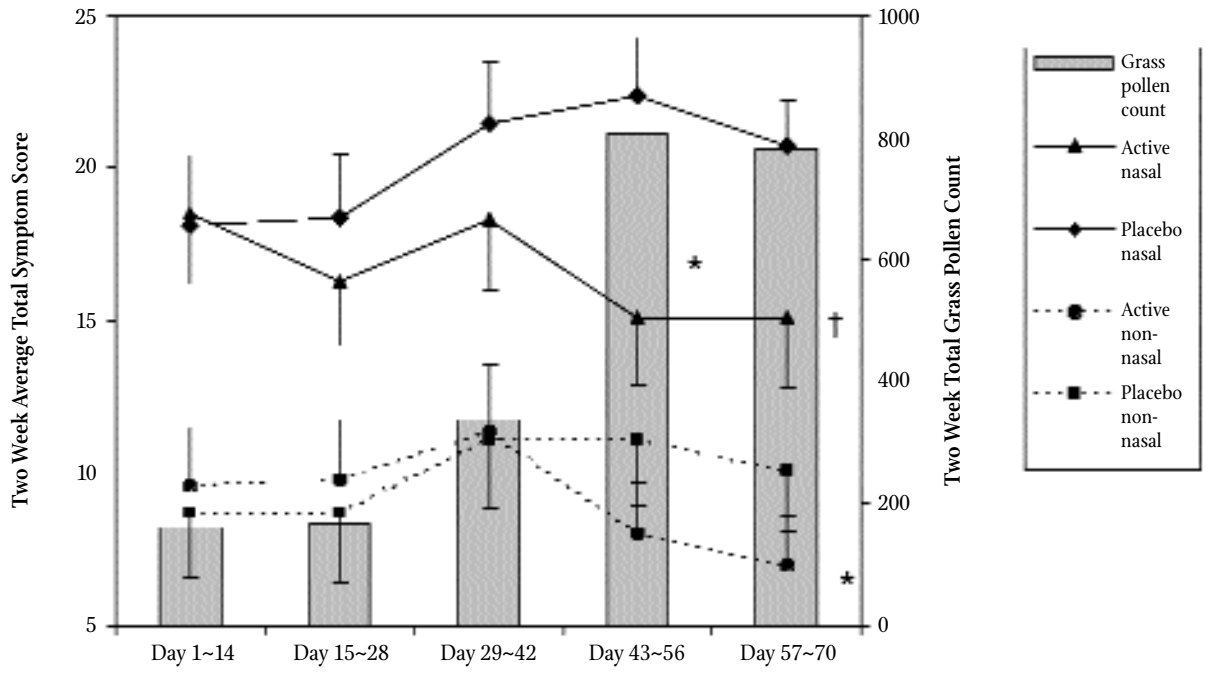

FIGURE 2 Two-week average total nasal and non-nasal symptom scores (Five-point scale) and two-week total grass pollen count during the Trial. Mean total symptom scores and standard deviations are plotted for active nasal symptom score (▲), active non-nasal symptom score (●), placebo nasal symptom score (◆) and placebo non-nasal symptom score (■). To avoid overlap, standard deviations are plotted in one direction only. * Indicates $P < 0.05$, † indicates $P < 0.01$. The vertical bars show the pollen count.

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