CCL Xue 薛長利
FCK Thien 鄧忠光
JJS Zhang 張健生
W Yang 楊　瑋
C Da Costa
CG Li 李春光

Effect of adding a Chinese herbal preparation to acupuncture for seasonal allergic rhinitis: randomised double-blind controlled trial

針灸配合中藥治療季節性過敏性鼻炎：雙盲隨機對照試驗

Objective. To assess whether the addition of a Chinese herbal medicine formula to acupuncture affects the severity of symptoms and quality-of-life scores among patients with seasonal allergic rhinitis.
Design. Randomised double-blind placebo-controlled trial.
Setting. University teaching and research clinic, Australia.
Participants. Sixty-five patients with seasonal allergic rhinitis, who were recruited through public media.
Intervention. Between July and December 1999, patients received acupuncture twice a week for 8 weeks plus either a Chinese herbal drug formula (n=33) or placebo (n=32) at a dosage of four capsules, three times daily.
Main outcome measures. The severity of nasal and non-nasal symptoms on a five-point scale, as assessed by both patients and an ear, nose, and throat specialist, and quality-of-life scores as measured by the Rhinoconjunctivitis and Rhinitis Quality of Life Questionnaire.
Results. Sixty-one patients completed the study (31 in the intervention group and 30 in the control group). After 8 weeks, no significant difference was found between the two groups in the severity of nasal and non-nasal symptoms and in the Rhinoconjunctivitis and Rhinitis Quality of Life Questionnaire scores. Intention-to-treat analysis of categorical variables showed moderate-to-marked improvement rates of 72.7% and 81.2% for intervention and control groups, respectively. Six patients reported mild adverse events—three from each of the study groups.
Conclusion. The Chinese herbal formulation under investigation did not provide additional symptomatic relief or improvement in quality-of-life scores among patients with seasonal allergic rhinitis who were receiving acupuncture.

目的：評估在針灸治療季節性過敏性鼻炎同時配合中藥配方，是否能額外緩解患者的症狀，並提高其生活質素問卷得分。
設計：雙盲隨機試驗，以安慰劑為對照。
安排：大學教學與研究診所，澳洲。
參與者：公開招募65名季節性過敏性鼻炎患者。
療法：在1999年7月至12月間，所有患者每週接受針灸兩次，為期8週。其中33人同時給予中藥膠囊服用，劑量為每天3次，每次4粒；餘下32人則服用同劑量的安慰劑膠囊。
主要結果測量：由患者本人及一位耳鼻喉專科醫生，分別按5點量表評估鼻部及非鼻部症狀的嚴重程度；並採用「鼻結膜炎及鼻炎患者生活質量問卷」評估患者的生活質素。
測量結果：61位患者完成整項試驗；中藥配合針灸組佔31人，安慰劑對照組佔30人。8星期後，在鼻部及非鼻部症狀的嚴重程度，以及「鼻結膜炎及鼻炎患者生活質量問卷」的得分上，兩組患者均無顯著差異。分類變量的治療意向分析顯示中等至顯著改善率，中藥配合針灸組為72.7%，而安慰劑對照組則為81.2%。共有6名患者（每組3位）出現輕微的不良反應。
結論：接受針灸治療的季節性過敏性鼻炎患者同時服用本試驗中所用的中藥配方，並不能額外緩解症狀或提高其生活質素指標的得分。

Key words:
Acupuncture;
Clinical trials;
Hay fever;
Medicine, traditional;
Treatment outcome

關鍵詞：
針灸；
臨床試驗；
枯草熱；
藥物，傳統；
治療結果

Hong Kong Med J 2003;9:427-34

RMIT University, Bundoora West Campus, Bundoora, Victoria 3083, Australia:
RMIT Chinese Medicine Research Group
CCL Xue, PhD
CG Li, PhD
Chinese Medicine Unit
JJS Zhang, PhD
Department of Mathematics and Statistics
C Da Costa, PhD
Department of Allergy, Asthma and Clinical Immunology, Monash University, Alfred Hospital, Melbourne, Victoria 3004, Australia
FCK Thien, MD
School of Engineering and Science, Swinburne University of Technology, Howthorn, Victoria 3122, Australia
W Yang, MEng

Correspondence to: Dr CCL Xue (e-mail: charlie.xue@rmit.edu.au)

Introduction

Allergic rhinitis is a common condition that can significantly affect the quality of life.[1,2] In some countries, the prevalence ranges from 1.4% to 39.7% among 13- to 14-year-olds; in other countries, such as Australia, the prevalence is higher.[3] Current western medical approaches to managing allergic rhinitis include drug therapy and immunotherapy. These therapies, however, are associated with side-effects and, in many cases, do not provide complete relief of all symptoms.[2] Hence, alternative treatments for allergic rhinitis have been sought,[4] with a substantial proportion of patients using Chinese medicine.[5,6]

We previously demonstrated that either acupuncture[7] or Chinese herbal medicine[8] (CHM) alone can provide effective symptomatic relief for patients with seasonal allergic rhinitis. Acupuncture resulted in a significantly better outcome in symptomatic relief than did sham acupuncture, the reduction in symptom severity being 66% and 26%, respectively.[7] Similarly, use of CHM yielded a significantly better outcome than did placebo herbal capsules: the reduction in severity of symptoms of seasonal allergic rhinitis was 63% and 39%, respectively.[8] In Chinese medicine, CHM and acupuncture are frequently used concurrently to manage seasonal allergic rhinitis. It is generally assumed that the combined approach may generate a better clinical outcome.[9] This assumption, however, is yet to be scientifically tested. In this study, we aimed at determining whether CHM produces an additional effect to acupuncture, by performing a randomised double-blind placebo-controlled trial. We used the same treatment protocols as those used in the previous acupuncture[7] and CHM[8] studies, because these therapies were effective individually in achieving symptomatic relief of seasonal allergic rhinitis. The results of this study may provide useful information for Chinese medicine practitioners to determine whether one or two types of Chinese medicine should be used in the symptomatic management seasonal allergic rhinitis.

Methods

Patient selection and randomisation

The trial was approved by the Royal Melbourne Institute of Technology (RMIT) University Human Research Ethics Committee and registered with the Therapeutic Goods Administration, Australian Department of Health and Ageing. Between July and September 1999, patients were recruited through the public media (including local newspapers and radio) by the Chinese Medicine Research Clinic at the RMIT University in Melbourne, Australia. After completing a screening questionnaire, patients were interviewed to confirm western and Chinese medicine diagnoses. Treatment and assessment were conducted at the same clinic. Randomisation was performed by an investigator who was not involved in the clinical part of the study, and involved allocating a computer-generated random number to each patient and then ranking patients on the basis of the assigned random number. The top and bottom 50% were then allocated to the treatment and control groups, respectively. All patients were informed that they would receive acupuncture plus either active or placebo CHM treatment.

Patients who met the following criteria were included in the study: age 18 to 70 years inclusive; a history of typical symptoms of seasonal allergic rhinitis, such as watery rhinorrhoea, sneezing, nasal congestion, nose itch, and itchy eyes for 2 to 3 years; a positive skin prick test result to grass pollens; and provision of written informed consent. Patients with one or more of the following criteria were excluded from the study: HIV infection; history of specific immunotherapy; other active respiratory diseases, such as asthma; nasal polyposis; systematic corticosteroid therapy; current pregnancy; and hepatitis B and C.

The same ear, nose, and throat (ENT) specialist assessed the severity of nasal and non-nasal symptoms of each patient. The timing of the trial was based on previous studies of pollen counts and on the Melbourne pollen calendar.[10] The experimental phase of this study was conducted between July and December of 1999 and data were collected between October and December 1999.

Acupuncture treatment

A previously published Chinese medicine diagnostic procedure was used to guide the selection of acupuncture points.[11] The key points selected for all patients were *yingxiang* (LI 20), *yintang* (extra point), and *fengchi* (GB 20). Supplementary points for different syndromes were *feishu* (BL 13), *taiyuan* (LU 9) for *lung qi* deficiency syndrome; *pishu* (BL 20), *zusanli* (ST 36) for spleen *qi* deficiency syndrome; and *shenshu* (BL 23) and *qihai* (CV 6) for kidney *qi* deficiency syndrome.[12]

We used Hwato (Suzhou Medical Appliance Factory, Suzhou, China) disposable presterilised acupuncture needles (0.3 mm in diameter). The needle length depended on the location of the acupuncture point. Patients were first asked to lie in the supine position for needling of the main points, and then in the prone position for needling of the back *shu* points, followed by needling of supplementary points. Sites were swabbed with 70% isopropyl alcohol before needle insertion, and dry sterile cotton wool was used when withdrawing the needles. Acupuncture needling was performed according to standard techniques.[12] In brief, needles were inserted transversely, obliquely, or perpendicularly depending on the points selected, to a depth between 10 mm and 40 mm. The needles remained in place for 25 minutes while applying one of the needle techniques (even movement, reducing, or tonifying, via rotation, lifting, or thrusting) and repeating the needling techniques every 10 minutes before needle withdrawal (Table 1). All treatments were performed by the same acupuncturist throughout the trial. All patients received acupuncture

Table 1. Needling procedure for acupuncture treatment

Point*	Direction	Depth (mm)	Technique
Yingxiang (LI 20)	Transversely, upwards, and medially to bridge of nose	20	Even movement
Yintang (EX 1)	Transversely, downwards, and towards root of nose	15	Even movement
Fengchi (GB 20)	Obliquely, downwards, and centrally to tip of nose	15	Reducing
Feishu (BL 13)	Obliquely to spine	20	Tonifying
Taiyuan (LU 9)	Obliquely and upwards to radius	10	Tonifying
Pishu (BL 20)	Obliquely to spine	20	Tonifying
Zusanli (ST 36)	Obliquely between tibia and fibula	40	Tonifying
Shenshu (BL 23)	Obliquely to spine	20	Tonifying
Qihai (CV 6)	Perpendicularly at anterior midline below umbilicus	20	Tonifying

* Terms in parentheses are standardised abbreviations and numbers of acupuncture points[12]

Table 2. Ingredients of the herbal formula*

Ingredient	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 The Pharmacopoeia Commission of China[22]

treatment twice a week (at least 2 days apart) for 8 weeks, with a total of 16 acupuncture treatments.

Herbal preparation and treatment schedule

The active Chinese herbal formulation contained 18 different herbs (Table 2), which were selected on the basis of traditional use in CHM for symptoms of seasonal allergic rhinitis. All herbal extracts were granulated by a herbal pharmaceutical company in Taiwan (Min Tong Pharmaceutical Company), which had certification for having good manufacturing practice, and the granules were encapsulated (500 mg each) by New Product Development Pty Ltd, Queensland, Australia. The treatment codes of all herbal substances used in the study are listed in the Australian Register of Therapeutic Goods and thus have been approved for human use. The herbal components were administered within the recommended dosages. Furthermore, all substances used were readily available over the counter throughout Australia; no animal products or restricted herbal ingredients were used in this study. The placebo capsules, containing 500 mg of soy polysaccharides, were also prepared by New Product Development Pty Ltd. The capsules were matched in size, colour, and appearance with those containing the active formulation. (A food allergy history was obtained from all patients and none reported an allergy to soy.)

A randomised double-blind placebo-controlled trial design was used for the CHM treatment. All patients were monitored for a 2-week baseline period after initial assessment. The randomised patients received acupuncture plus either the active or placebo CHM treatment (four capsules per dose, three times daily) for 8 weeks. The patient treatment code was strictly masked throughout the trial and data analysis period.

Outcome measures

The primary endpoint with respect to efficacy was severity of nasal and non-nasal symptoms of seasonal allergic rhinitis on a five-point scale, as determined both by patients themselves and by an ENT specialist. The following scores were assigned: 0=no symptoms; 1=very slight symptoms but noticeable; 2=moderately severe symptoms; 3=severe symptoms; and 4=very severe symptoms, as described by Prenner et al.[13] Patients also completed a study diary to score nasal symptoms (sneezing, rhinorrhoea, nasal congestion, and nasal itch) and non-nasal symptoms (itching, watering, or redness of eyes, and itchy ears or palate). They were also required to attend the clinic fortnightly for evaluation by the same specialist. The secondary endpoint was the change in score recorded by patients for the variables measured in the Rhinoconjunctivitis and Rhinitis Quality of Life

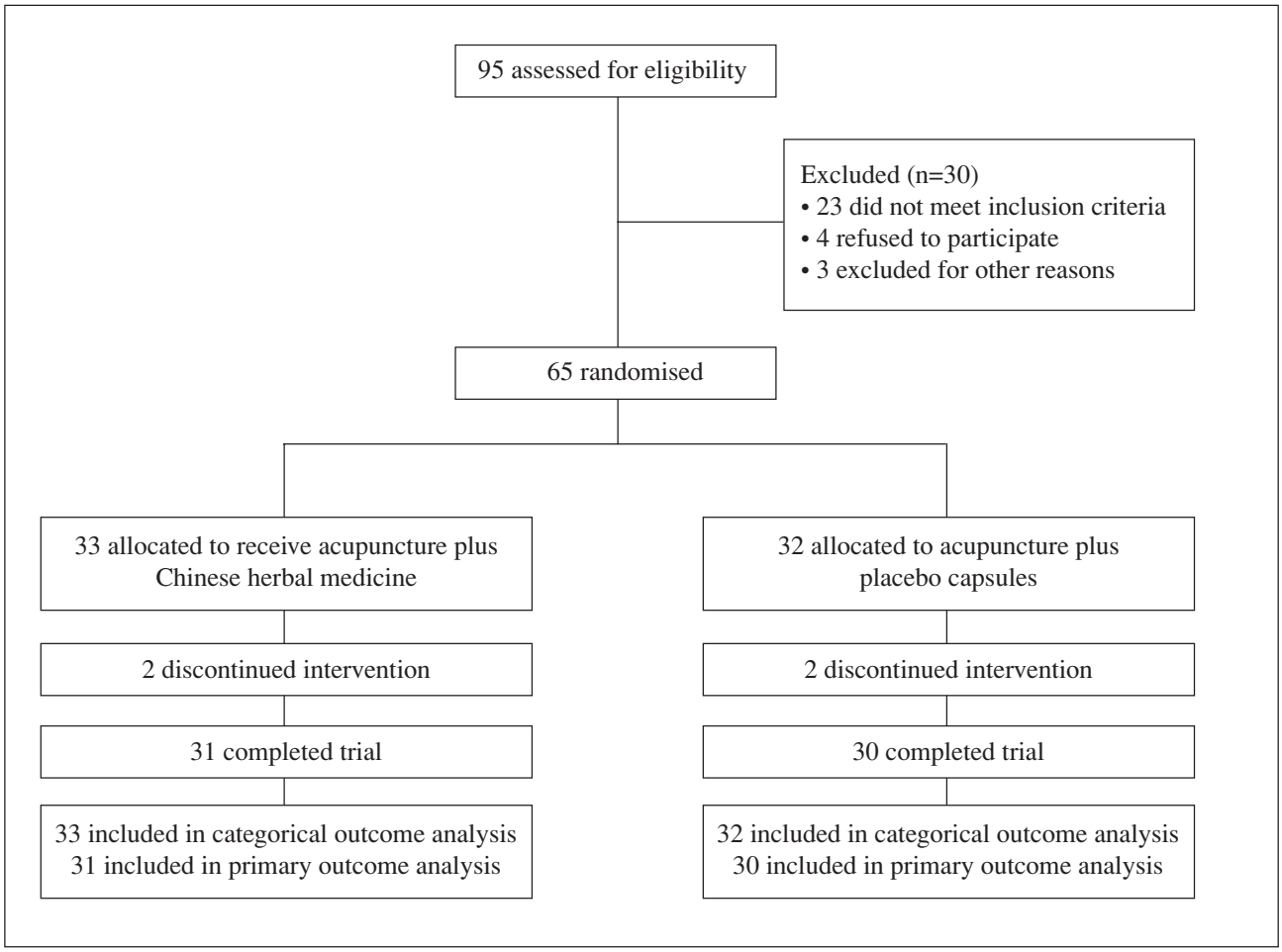

Fig 1. Patient flow through the trial

Questionnaire (RQLQ)—a previously validated instrument used to monitor quality of life.[1]

Overall individual responses to treatment were rated by using the following seven-point scale: 0 indicated no change; 1, 2, and 3 indicated mild, moderate, and marked improvement, respectively; and -1, -2, and -3 indicated mild, moderate, and significant worsening, respectively. Patients were also asked to provide details of other medication that they took for symptomatic relief during the study (name of medication, the date and time of use, and whether there was any beneficial effect). For each patient, a drug-use score was calculated as follows: for each type of drug taken, the total number of doses was multiplied by a nominal category score (nasal spray, topical ocular or decongestants=1; oral antihistamines=2; and prescription-only drugs, such as steroid nasal sprays=3). Where multiple drugs were used the drug-use scores were added together. Furthermore, to monitor patient compliance, a blinded research assistant recorded the leftover CHM capsule count at the end of the study.

All patients were provided with a form to record potential adverse effects during the treatment period. Details of adverse events were scored using the following six-point scale to indicate the severity of these events: 0=none, 1=minimal, 2=mild, 3=moderate, 4=severe, and 5=extremely severe. Finally, patients' opinions of CHM were assessed with a Visual Analogue Scale, a validated instrument described elsewhere.[14] This questionnaire was completed by all patients at the beginning and end of the study.

Statistical analysis

All data were processed and analysed by the Department of Mathematics and Statistics at the RMIT University. Data were expressed as means and standard deviations (SD). Because acupuncture and CHM alone each produced greater than 60% of symptomatic relief for patients treated,[7,8] we considered a 30% additional benefit from the combination of the two treatment modalities to be clinically significant. Accordingly, sample size calculations were based on detecting a difference of 30% at the end of 8 weeks of treatment: a sample size of 32 patients in each group would ensure 80% power with a type I error rate of 5% (two-tailed). Intention-to-treat analysis was conducted for all randomised patients with outcome data. In addition, for categorical variables, the overall individual responses to treatment, patients who withdrew from the study were

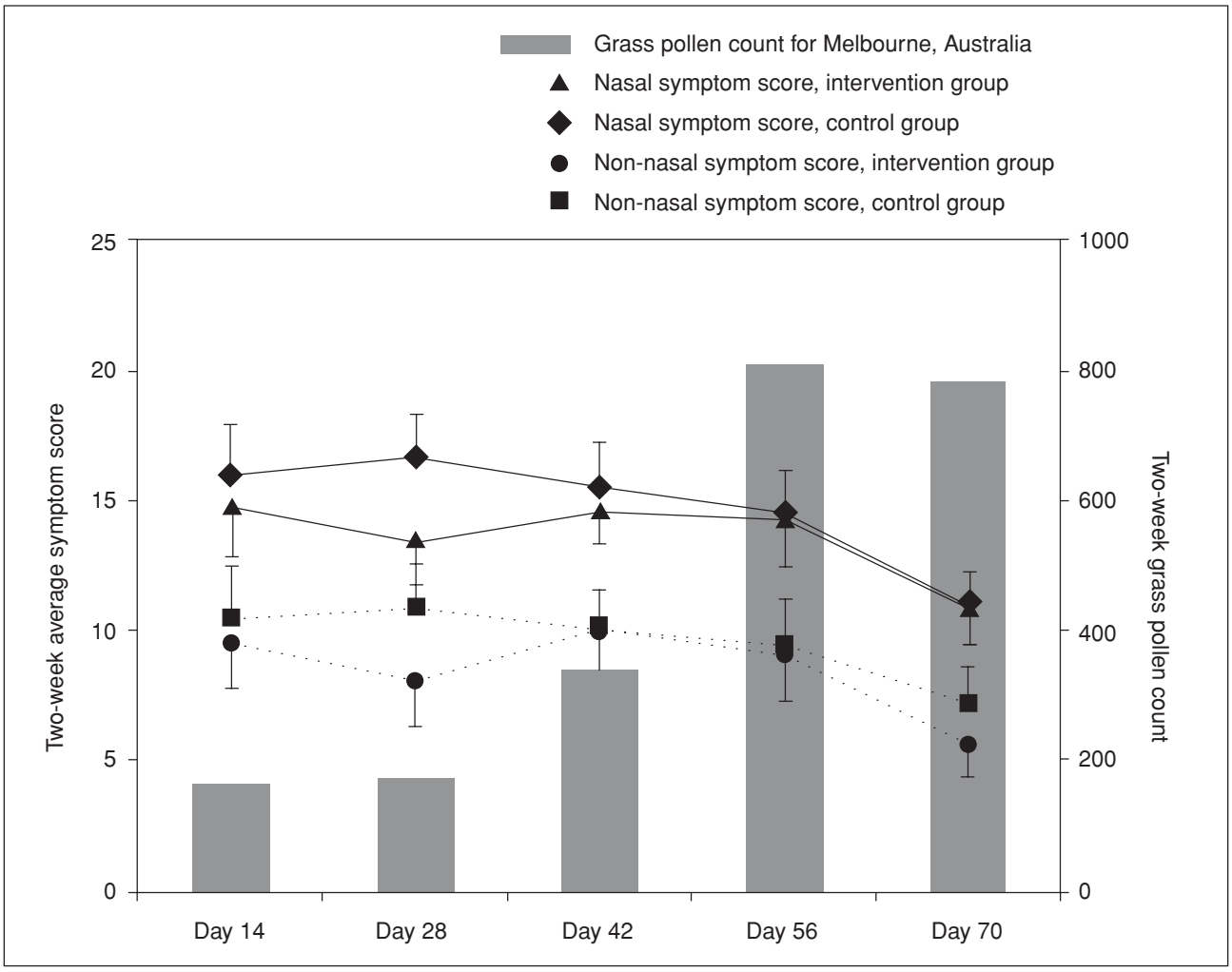

Fig 2. Two-week nasal and non-nasal symptom scores and grass pollen counts during the trial (means and standard deviations in one direction)

recorded as having a worsened condition. The data were analysed using the Statistical Package for the Social Sciences (Windows version 10; SPSS Inc, Chicago, US). The statistical tests used were analysis of variance (general linear model) for repeated measures, Student's *t* tests for non-repeated measures, and Chi squared and Fisher exact tests for categorical measures. All P values were two-tailed and considered significant at $P \leq 0.05$.

Results

Sixty-five adult patients (36 men and 29 women) with the mean age of 43 years were enrolled in the trial. In addition to receiving acupuncture, 33 participants received CHM capsules and 32 received placebo capsules. Four patients dropped out of the study before the scheduled completion date: two because of treatment failure for symptomatic relief perceived by patients and two because of non-compliance (Fig 1). There were no statistically significant differences between the intervention and control groups in terms of sex, age, or baseline disease characteristics (duration of seasonal allergic rhinitis, family history of allergy, and the baseline mean total symptom score) [Table 3].

Symptom scores

In general, baseline scores for nasal symptoms as assessed by the patient and the ENT specialist were similar, but the ENT specialist gave somewhat lower scores for the non-nasal symptoms than did patients. In contrast, endpoint scores assigned by patients and the specialist were similar (Table 3). There was no significant difference between the two study groups in any of the baseline or endpoint scores for nasal and non-nasal symptoms (Table 3). There was also no significant difference between the two groups in mean nasal and non-nasal symptom scores on days 14, 28, 42, 56, and 70 (Fig 2). For both study groups, the scores were considerably lower at the end of the trial. Within group comparison, the percentage reduction for nasal and non-nasal symptoms were 66% and 79% respectively for the acupuncture plus real CHM group, 65% and 60% respectively for the acupuncture plus placebo herbal medicine group (Table 3). It is also worth-mentioning that

Table 3. Patient characteristics and outcome scores at baseline and after treatment, by study group*

	Chinese herbal medicine	Placebo
Characteristic	n= 33	n= 32
Age (years)	44.7 (11.6)	42.4 (13.0)
Sex (male:female)	18 :15	18 :14
Duration of seasonal allergic rhinitis (years)	28.0 (14.5)	24.0 (16.4)
Family history of seasonal allergic rhinitis (yes:no)	24 :9	20 :12
Total nasal + total non-nasal symptom score	18.5 (5.0)	17.4 (5.6)
Baseline	n= 33	n= 32
Mean nasal symptom score (assessed by patient)	2.57 (0.68)	2.38 (0.76)
Mean non-nasal symptom score (assessed by patient)	2.16 (0.70)	1.97 (0.81)
Mean nasal symptom score (assessed by specialist)	2.13 (0.65)	2.03 (0.51)
Mean non-nasal symptom score (assessed by specialist)	1.42 (0.80)	1.33 (0.75)
RQLQ† section 1 score	3.57 (1.40)	3.48 (0.97)
RQLQ section 2 score	2.78 (1.63)	2.66 (1.32)
End of treatment	n= 31	n= 30
Mean nasal symptom score (assessed by patient)	0.88 (0.61)	0.83 (0.63)
Mean non-nasal symptom score (assessed by patient)	0.46 (0.62)	0.51 (0.64)
Mean nasal symptom score (assessed by specialist)	0.85 (0.59)	0.78 (0.59)
Mean non-nasal symptom score (assessed by specialist)	0.46 (0.59)	0.45 (0.60)
RQLQ section 1 score	1.02 (0.95)	0.89 (0.79)
RQLQ section 2 score	5.03 (1.05)	5.38 (0.93)

* Results, except for sex and family history, are expressed as mean (standard deviation); all results of intervention and control groups are not significantly different from each other (P>0.05)
† RQLQ Rhinoconjunctivitis and Rhinitis Quality of Life Questionnaire

Table 4. Patient rating of overall response to treatment, by study group*

Reported change in condition	No. (%)	
	Chinese herbal medicine, n=33	Placebo, n=32
Significant improvement	17 (51.5)	17 (53.1)
Moderate improvement	7 (21.2)	9 (28.1)
Mild improvement	5 (15.2)	3 (9.4)
No change	1 (3.0)	1 (3.1)
Mild worsening	1 (3.0)	0 (0.0)
Moderate worsening	0 (0.0)	0 (0.0)
Significant worsening	2 (6.1)†	2 (6.3)‡

* All results of intervention and control groups are not significantly different from each other (P>0.05)
† Two patients dropped out before the completion of the trial due to treatment failure assessed by patients
‡ Two patients dropped out before the completion of the trial due to non-compliance of patients

the pollen counts increased steadily throughout the trial period (Fig 2).

Quality-of-life scores

The RQLQ comprises two sections: one records symptoms and activities related to seasonal allergic rhinitis and the other records the emotional impact of seasonal allergic rhinitis. There was no significant difference in the fortnightly mean scores in both RQLQ sections between the intervention and control groups, both at baseline and at the end of the trial (Table 3).

Overall individual response to treatment

Overall individual response to treatment is shown in Table 4, which includes the four patients who dropped out of the study. There was no significant difference between the drug and placebo groups in ratings of seasonal allergic rhinitis symptoms. Thus, 51.5% and 53.1% of the intervention and control groups, respectively, said that they felt a significant improvement. Smaller proportions reported moderate-to-mild improvement. Intention-to-treat analysis of categorical variables showed moderate-to-marked improvement rates of 72.7% and 81.2% for intervention and control groups, respectively.

Compliance

No significant difference was observed in the relief medication scores (not shown). The mean (SD) endpoint score among the intervention group was 1.33 (3.12), compared with 4.44 (10.18) among the placebo group. The mean 2-week leftover capsule counts at the endpoint were 12.54 (25.61) and 21.60 (27.67), respectively. There were no statistically significant differences between the intervention and control groups in the leftover capsule count and usage of other drugs.

Patients' opinions of Chinese herbal medicine

No statistically significant differences were observed between the drug and placebo groups in patients' opinions of CHM, in terms of confidence, rational use, recommendation of CHM to other people, and confidence in CHM for other clinical conditions (not shown). At day 0, the mean score among the group receiving the active herbal remedy was 73.13 (21.41) and that among the placebo group was 72.60 (18.15), and at day 70, the corresponding values were 72.50 (20.64) and 67.00 (20.67).

Safety of the herbal remedy

Approximately 10% of patients in the active group (three of 33) and 13% of those in the placebo group (three of 32) experienced mild side-effects, such as bloating, indigestion, mild stomach ache, and mild bruising from acupuncture. Gastrointestinal discomfort was reported mainly at

the beginning of the trial, and the degree of discomfort decreased after 2 weeks of CHM use. The gastrointestinal side-effects were tolerable, however, and did not require additional treatment—that is, they were mild and resolved spontaneously.

Discussion

This study is a continuation of previous studies[7,8] completed at the RMIT University to test whether combination of acupuncture and CHM generates a better clinical outcome than either modality alone.[15] It is common for Chinese medicine practitioners to choose combined applications of both acupuncture and CHM in the clinical management of common conditions,[9,16] such as seasonal allergic rhinitis, particularly when studies have demonstrated that either acupuncture or CHM alone is effective.[7,8] This belief and approach, however, needs to be critically tested. Our finding that patients who received acupuncture plus active CHM showed no additional benefit, in relief of both nasal and non-nasal seasonal allergic rhinitis symptoms, indicates that the CHM formula and acupuncture combination may not be necessary, at least for some patients, in the management of seasonal allergic rhinitis. Even so, this short-term study is not relevant to the assessment of possible long-term benefits of the combination of treatments.

There is limited evidence from randomised clinical trials that combination of acupuncture and the herbal formulation used in this study may be beneficial to patients with seasonal allergic rhinitis.[7,8] However, as far as we are aware, this is the first randomised double-blind placebo-controlled clinical trial using a strict and widely accepted methodological protocol to compare the efficacy of the combination of these two treatments in the management of seasonal allergic rhinitis. In particular, we used well-defined inclusion and exclusion criteria[17] and independent assessments by patients and an ENT specialist. The patients included in the trial demonstrated homogeneity in relation to age, sex, duration of seasonal allergic rhinitis, and severity of their condition. All the instruments measuring outcome in this trial have been validated.[1,13,18] A credibility scale was also incorporated into this trial to monitor patients' opinions of their treatment.[14,19] The similar levels of compliance with herbal medicine and similar opinions on CHM throughout the trial indicate that the blinding procedure was successful and that the psychological influence on the outcome measures in this study was minimal.

The traditional view among Chinese medicine practitioners on acupuncture is that it is more effective in the management of acute and secondary syndromes, whereas CHM is more effective in treating chronic and primary disorders.[15] However, both the acupuncture-plus-CHM and the acupuncture-plus-placebo groups had considerably reduced (60%-79%) severities of symptoms of seasonal allergy. The findings are strengthened by the consistency of the assessment made by patients and the ENT specialist in respect of severity of nasal and non-nasal symptoms, RQLQ scores, and the overall response rating. The lack of difference in results between the two study groups suggests that the CHM formulation used in this study did not produce an additional benefit as the percentage reduction in symptom severity was not greater than that for acupuncture (67%) alone.[7] The potential mechanisms of these outcomes were unknown.

The overall tolerability of the herbal formulation was good, although certain side-effects were reported—most commonly, bloating and indigestion. Three of 33 patients in the active treatment group and three of 32 patients in the placebo group reported these unexpected discomforts. Because there was no difference between the active and placebo groups in the probability of experiencing discomfort, it is unlikely that there is a connection between these side-effects and the herbal preparation in the CHM capsules. The gastrointestinal discomfort may relate to the consumption of a relatively large number of capsules; patients commonly mentioned they did not expect to take 12 capsules a day. It is likely that the gastrointestinal discomfort was due to the intake of the large number of capsules. However, certain herbal medicine ingredients used (*Chai Hu, Sheng Ma*, *Chuan Xiong*, *Wu Wei Zi*, and *Cang Er Zi*) may also have the potential to produce gastrointestinal discomfort.[20,21] It is worth mentioning that the formula did not contain *Ma Huang*—a source of ephedrine that has been reported to be associated with central nervous system and cardiovascular side-effects.[21] Because the overall frequency of side-effects was almost the same between the two groups, it is reasonable to suggest that the CHM formulation used in this trial is safe for patients with seasonal allergic rhinitis within the period of 8 weeks.

In conclusion, this randomised double-blind placebo-controlled trial demonstrates that the addition of a CHM formulation to acupuncture therapy does not improve the severity of symptoms or the quality-of-life scores over the effects produced by acupuncture alone in the treatment of seasonal allergic rhinitis.

Acknowledgements

The project would not have been completed without the ongoing assistance of Dr B Polus, Department of Complementary Medicine, the RMIT University; Prof CJ Xun, ENT specialist; Dr JL Xue, associate professor in Chinese Medicine from the China Academy of Traditional Chinese Medicine; Dr QT Chen; and Ms D Do. We also thank Ms A Liu for her assistance in taking blood samples, and Prof D Story, the RMIT University, for critical and constructive comments during manuscript preparation. The study was supported in part by The Everbest Australia Pty Ltd, Australia. We would also like to acknowledge the assistance provided by New Product Development, Queensland, Australia for the encapsulation process. The supporting sources were not involved in the study design, data

collection, analysis, interpretation, or preparation of this manuscript.

References

1. Juniper EF, Guyatt GH. Development and testing of a new measure of health status for clinical trials in rhinoconjunctivitis. Clin Exp Allergy 1991;21:77-83.
2. van Cauwenberge P, Bachert C, Passalacqua G, et al. Consensus statement on the treatment of allergic rhinitis. European Academy of Allergology and Clinical Immunology. Allergy 2000;55:116-34.
3. Worldwide variation in prevalence of symptoms of asthma, allergic rhinoconjunctivitis, and atopic eczema: ISAAC. The International Study of Asthma and Allergies in Childhood (ISAAC) Steering Committee. Lancet 1998;351:1225-32.
4. Engler RJ. Alternative and complementary medicine: a source of improved therapies for asthma? A challenge for redefining the specialty? J Allergy Clin Immunol 2000;106:627-9.
5. Blanc PD, Trupin L, Earnest G, Katz PP, Yelin EH, Eisner MD. Alternative therapies among adults with a reported diagnosis of asthma or rhinosinusitis: data from a population-based survey. Chest 2001;120: 1461-7.
6. Hu G, Walls RS, Bass D, et al. The Chinese herbal formulation biminne in management of perennial allergic rhinitis: a randomised, double-blind, placebo-controlled, 12-week clinical trial. Ann Allergy Asthma Immunol 2002;88:478-87.
7. Xue CC, English R, Zhang JJ, Da Costa C, Li CG. Effect of acupuncture in the treatment of seasonal allergic rhinitis: a randomised controlled clinical trial. Am J Chin Med 2002;30:1-11.
8. Xue CC, Thien FC, Zhang JJ, Da Costa C, Li CG. Treatment for seasonal allergic rhinitis by Chinese herbal medicine: a randomized placebo controlled trial. Altern Ther Health Med 2003;9:80-7.
9. Xue CC, WH Yang. Academic achievements in acupuncture-The emphasis of the combination of acupuncture and Chinese herbal medicine in clinical management. In: Lai XS, Zhang JW, editors. A compendium of clinical experience of acupuncture experts in Southern China [in Chinese]. 1st ed. Beijing: China Medical Technology Publishing House; 1998:15-7.
10. Ong EK, Singh MB, Knox RB. Grass pollen in the atmosphere of Melbourne: seasonal distribution over nine years. Grana 1995;34:58-63.
11. The state administration of traditional Chinese medicine (SATCM). Criteria of diagnosis and therapeutic effect of diseases and syndromes in TCM [in Chinese]. 1st ed. Nanjing: Nanjing University Press; 1994.
12. Qiu ML. Chinese acupuncture and moxibustion. 1st ed. New York: Churchill Livingstone; 1993.
13. Prenner BM, Chervinsky P, Hampel FC Jr, et al. Double-strength beclomethasone dipropionate (84 micrograms/spray) aqueous nasal spray in the treatment of seasonal allergic rhinitis. J Allergy Clin Immunol 1996;98:302-8.
14. Bensoussan A, Talley NJ, Hing M, Menzies R, Guo A, Ngu M. Treatment of irritable bowel syndrome with Chinese herbal medicine: a randomized controlled trial. JAMA 1998;280:1585-9.
15. Wei J. Schools of thought in acupuncture [In Chinese]. 1st ed. Shanghai: Shanghai Science & Technology Press; 1987.
16. Xue CC. Combination of acupuncture with Chinese herbal medicine for 108 cases of hemiplegia [In Chinese]. Guangdong Medical Journal 1993;3:149-50.
17. Ortolani C, Pastorello EA, Incorvaia C, et al. A double-blind, placebo-controlled study of immunotherapy with an alginate-conjugated extract of Parietaria judaica in patients with Parietaria hay fever. Allergy 1994; 49:13-21.
18. Andri L, Senna GE, Betteli C, et al. Local nasal immunotherapy in allergic rhinitis to Parietaria. A double-blind controlled study. Allergy 1992;47:318-23.
19. Vincent C. Credibility assessment of trials in acupuncture. Complement Medicine Research 1990;4:8-11.
20. Zhu YP. Chinese Materia Medica: chemistry, pharmacology and application. 1st ed. The Netherlands: Harwood Academic Publishers; 1998.
21. Huang KC. The Pharmacology of Chinese herbs. 2nd ed. Boca Raton (Fla): CRC Press; 1999.
22. Pharmacopoeia of PR China (Vol 1). Beijing: Chemical Industry Press; 1997.

Full time clinic doctor required. 9 a.m. – 9 p.m. with long lunch break. Local or overseas candidate welcomed. Weekly day off. Income on sharing basis with guaranteed salary. Interested parties please fax CV to 3016 8500 or call Miss Tsang at 8101 1187.