PHYTOTHERAPY RESEARCH
Phytother. Res. **24**: 609–613 (2010)
Published online 14 December 2009 in Wiley InterScience
(www.interscience.wiley.com) **DOI**: 10.1002/ptr.3058

A Panel Study to Evaluate Quality of Life Assessments in Patients Suffering from Allergic Rhinitis after Treatment with a Chinese Herbal Nasal Drop

Shiu Hon Chui[1]*, Siu Lam Shek[2], Ming Yiu Fong[3], Yim Tong Szeto[1] and Kelvin Chan[4]

[1]Macau Institute for Applied Research in Medicine and Health, Macau University of Science and Technology, Macau SAR, China
[2]Private Clinic, Suite 613 Melbourne Plaza, 33 Queen's Road Central, Hong Kong SAR, China
[3]Diagnostix Medical Centre Ltd, Suite 705, Melbourne Plaza, 33 Queen's Road Central, Hong Kong SAR, China
[4]Pharmacy Department, School of Applied Sciences, University of Wolverhampton, Wulfruna Street, Wolverhampton WV 1 1SB, UK

Allergic rhinitis impairs quality of life (QOL). To assess the changes in QOL of patients with perennial allergic rhinitis (PAR) after treatment with Allergic Rhinitis Nose Drops (ARND), 35 patients were divided into 2 groups in a randomized, double-blinded and placebo-controlled study, with a cross-over arrangement over 7 weeks, applying ARND or placebo. Group A (n = 20) started with ARND first for 2 weeks followed by a 3-week washout before placebo for the last 2 weeks, while Group B (n = 15) started with placebo first and finished with ARND after washout. The changes in Clinical Symptoms Score (CSS) and QOL were observed. A decrease in CSS was observed in patients of both groups after treatment with ARND, but no change was observed with the placebo. Group A patients also showed significant improvements in complexion and sleep ($P < 0.05$ for both) after treatment with ARND, but no change with the placebo. Group B patients showed significant improvements in appetite and digestion ($P = 0.01$) as well as joy ($P < 0.05$) after cross-over treatment with ARND, but no change with the placebo. ARND may have a therapeutic effect by relieving clinical symptoms and improving the QOL in patients with PAR. Copyright © 2009 John Wiley & Sons, Ltd.

Keywords: rhinitis; quality of life; Chinese medicine; nasal drop.

INTRODUCTION

Rhinitis or inflammation of the nasal membrane is characterized by a symptom complex including sneezing, nasal congestion, nasal itching, and rhinorrhea (Sibbald and Rink, 1991). It affects approximately 20% to 25% of the population (Sibbald and Rink, 1991). Allergy is the most common cause of rhinitis, leading to allergic rhinitis (AR) (Evans, 1993). While symptoms of AR are not life-threatening, they can affect the physical, psychological, and social aspects of patients' well-being, and can significantly decrease their quality of life (Juniper, 1998a; 1998b).

The assessment of patients' health-related quality of life (HRQOL) becomes increasingly important in clinical studies. While most HRQOL instruments currently in use in the West have been developed based on the health concepts according to western medical practice (Ware and Sherbourne, 1992; Ware *et al.*, 1996; Bergner *et al.*, 1981), a new generic HRQOL instrument more sensitive and appropriate for the assessment of the efficacy of Chinese medicine has been developed and coined as the Chinese Quality of Life Instrument (ChQOL) (Leung *et al.*, 2005). It was developed based on Chinese medicine and integrated Chinese culture to reveal the usefulness of Chinese medicine in healthcare, and is therefore more sensitive to detect the efficacy of Chinese medicine. It consists of four domains, namely (1) physical form composed of the facets complexion, sleep, stamina, appetite and adaptation to climate; (2) vitality composed of consciousness, thinking, spirit of the eye and verbal expression; (3) emotion composed of joy, anger, depress and fear; and finally, (4) the domain of overall quality of life. An increase in scores reveals an improved quality of life. The ChQOL can be used for the evaluation of the impact of the disease and its treatment with Chinese medicine on the patient's QOL (Zhao and Chan, 2005).

Treatment of AR with pharmaceutical medications including antihistamines, decongestants and corticosteroids, etc., is known to be associated with adverse effects. On the other hand, the use of Chinese medicines (CM) or medicinal formula for treatment of AR is believed to cause fewer side effects. Previous clinical studies using CM for treatment showed successful evidence using QOL approaches (Xue *et al.*, 2003; Brinkhaus *et al.*, 2004). Similarly many studies of AR using pharmaceuticals (Juniper and Guyatt, 1991; Reilly *et al.*, 1993; Meltzer *et al.*, 1995; Reilly *et al.*, 1996) also employed HRQOL instruments for QOL assessments. In the present study, the efficacy of a Chinese herbal/

* Correspondence to: Shiu Hon Chui, Macau Institute for Applied Research in Medicine and Health, Macau University of Science and Technology, Avenida Wai Long, Taipa, Macau SAR, China.
E-mail: shchui@diagnostix.com.hk

Received 23 July 2008
Revised 18 September 2009
Accepted 30 September 2009

medicinal formula – Allergic Rhinitis Nose Drops (ARND) – was assessed for the treatment of AR using the responsiveness of the ChQOL instrument as the patients' reported outcomes.

MATERIALS AND METHODS

Patients. Initially, we recruited 40 patients with clinically confirmed perennial allergic rhinitis (PAR) through a public seminar held at Hong Kong Baptist University. All participants were screened with questionnaires. All candidates having a PAR history of more than one year were recruited. Patients with major problems associated with cardiac, respiratory, renal and hepatic functions, and diabetes mellitus as well as other major medical illnesses were excluded. The recruited patients were not receiving specific immunotherapy or topical corticosteroids and were not using any traditional CM therapy for AR one month prior to entering the study. Of the 40 patients, 21 with a mean age of 35 ± 15.0 years (range 14–71 years) were women, and 19 with a mean age of 41 ± 15.8 years (range 8–76 years) were men. Only 35 patients completed the study. Among them, 11 patients had smoking history, 8 of them in Group A, and 3 of them in Group B.

Ethical approval was obtained from the Committee on the Use & Animal Subjects in Teaching and Research at the Hong Kong Baptist University by the number of KC/011–2005.

Allergic Rhinitis Nose Drops. ARND, manufactured by Lai Sing Medicine Factory Limited (Lai's Medicine), is a formula of 100% Chinese herbs and is claimed to be effective in relieving symptoms in patients with AR. The composition of ARND is as follows: Herba Centipedae 23%, Herba Menthae 16%, Radix Paeoniae Alba 16%, Radix Scutellariae 10%, Radix Glycyrrhizae 6%, Radix Platcodi 6%, Floz Lonicerae 5%, Fructus Zizyphi Jujubae 5%, Rhizoma Coptidis 4%, Radix Ledebouriellas 5%, Pericarpium Citri Reticuulatae 4%. The product has passed the international requirements for limits on heavy metal residues and pesticide residues as well as microbial contaminants. The study was sponsored by Lai's Medicine who provided all the medicines and the placebo drug required during the whole course of study.

Placebo. The placebo was made up of Radix Condonopsis Pilosulae and Radix Rehmanniae which have no specific treatment value or any known adverse effect on AR. It was prepared and packed by Lai's Medicine with the same package as the medicine. The smell of the placebo was adjusted to be similar to that of the medicine to ensure blindness of the study.

Methods. The study was a randomized, double-blinded and placebo-controlled model, with a cross-over arrangement for the administration of ARND or placebo. All patients were assessed by a specialist trained in internal medicine (SIM) and registered with the Medial Council of Hong Kong, who was blinded to the ARND patients for their clinical conditions prior to the entry of the study and at the end of the 2nd, 5th and 7th weeks. The patients were randomly divided into two groups: Group A (n = 20) was treated first with ARND on the first day of study after the blood sampling for baseline levels of laboratory tests (2 sprays per nostril, 5 times a day) followed by a washout period for 2 weeks and then placebo on the beginning of the 3rd week, while Group B (n = 20 but dropped to 15 completing the study) started with placebo first at the same time as Group A along the schedule shown in Table 1. All patients were also interviewed by a Chinese medicine practitioner (CMP) registered with the Chinese Medicine Council of Hong Kong, who was also blinded to the ARND and placebo groups arrangement. The CMP assessed all subjects at baseline, end of the 2nd, 5th and 7th weeks based on the practice of CM and the ChQOL.

Table 1. Arrangement of patient groups and schedule of treatment

Group	No. of patients	Treatment		
		0–2 weeks	3–5 weeks	6–7 weeks
A	20	ARND	Washout	Placebo
B	15	Placebo	Washout	ARND

Laboratory analysis and assessment of QOL were conducted at baseline, end of the 2nd, 5th and 7th weeks at their visits to the SIM and CMP respectively.

Clinical symptoms score. Before and after administration of ARND or placebo, the patients, under the guidance of the SIM, scored their rhinitis symptoms, based on the Clinical Symptoms Score (CSS), i.e., nasal obstruction (stuffiness), sneezing, nasal itching (itchiness), and running nose, on a scale of four, where 0 = no symptoms; 1 = slight symptoms; 2 = moderate symptoms; 3 = severe symptoms. The total score ranging from 0 to 12 for the four symptom types was recorded by the SIM. This score scale was adopted from a similar study protocol using fluticasone (Ventura *et al.*, 2001).

Laboratory analysis. Laboratory tests for fasting glucose, renal function (creatinine), liver function (ALT), haematological status (complete blood picture), and C-reactive protein (CRP) were performed at baseline, end of the 2nd, 5th, and 7th weeks with 10 ml of blood each time. All the above tests were performed by Diagnostix Medical Centre (DMC), a NATA (National Association of Testing Authorities, Australia) – accredited medical laboratory.

Quality of life assessment. The change in QOL of the patients was measured using an instrument, ChQOL (Cantonese Chinese version) designed by the research team at the Research and Development Division, School of Chinese Medicine, Hong Kong Baptist University to assess whether there was any improvement in the QOL of the subjects after treatment (Leung *et al.*, 2005).

Statistical analysis. Paired *t*-test was used to compare data before and after treatment with ARND as well as administration of placebo. A p value below 0.05 was regarded as significant.

DOI: 10.1002/ptr

RESULTS

Clinical symptoms score

Only 35 patients completed the study. Tables 2 and 3 show the results of the CSS of Group A and B patients respectively before and after administration of ARND or placebo. Relief of symptoms, i.e., sneezing, itchiness, running nose and stuffiness as reflected by the decrease in the total CSS values was observed in nearly all patients after treatment with ARND at the end of the 2nd week in Group A and at the end the of 7th week in Group B. Only improvements in sneezing and running nose were observed in Group A patients after applying placebo. On the other hand, no change of any symptom was observed at the end of the 2nd week for Group B patients after applying placebo.

Laboratory analysis

Neither abnormal results nor significantly adverse changes were documented for renal function, liver function and haematological tests as well as the CRP during the entire course of study as observed from the clinical tests, indicating that ARND did not have any adverse effect on the body. The results are shown in Tables 4 and 5.

Table 2. Changes in the CSS of Group A patients (n = 20). The scores are listed as mean ± SD. Weeks 3, 4 and 5 were the washout period. NS stands for non-significant

Clincial symptoms	On ARND			On Placebo		
	Baseline	End of 2nd week	p-value	End of 5th week	End of 7th week	p-value
Sneezing	1.58 ± 1.02	0.75 ± 0.53	<0.01	0.83 ± 0.65	0.58 ± 0.65	<0.05
Running nose	1.98 ± 1.06	1.05 ± 0.84	<0.01	1.08 ± 0.86	0.68 ± 0.57	<0.05
Itchiness	0.88 ± 0.84	0.54 ± 0.57	<0.01	0.48 ± 0.50	0.54 ± 0.71	NS
Stuffiness	1.33 ± 1.07	0.98 ± 0.70	<0.05	0.68 ± 0.57	0.74 ± 0.53	NS

Table 3. Changes in the CSS of Group B patients (n = 15). The scores are listed as mean ± SD. Weeks 3, 4 and 5 were the washout period. NS stands for non-significant

Clincial symptoms	On Placebo			On ARND		
	Baseline	End of 2nd week	p-value	End of 5th week	End of 7th week	p-value
Sneezing	1.13 ± 1.06	0.90 ± 0.87	NS	0.83 ± 0.96	0.53 ± 0.67	<0.05
Running nose	1.50 ± 0.99	1.34 ± 0.92	NS	1.25 ± 1.05	0.78 ± 0.71	0.01
Itchiness	0.63 ± 0.61	0.53 ± 0.44	NS	0.49 ± 0.79	0.36 ± 0.55	NS
Stuffiness	1.07 ± 0.66	1.01 ± 0.69	NS	0.92 ± 0.65	0.54 ± 0.42	<0.01

Table 4. Laboratory test results (mean ± SD) of Group A patients. Weeks 3, 4 and 5 were the washout period. NS stands for non-significant

	On ARND			On Placebo		
	Baseline	End of 2nd week	p-value	End of 5th week	End of 7th week	p-value
RBC ($\times 10^{12}$/L)	4.64 ± 0.46	4.56 ± 0.41	NS	4.60 ± 0.46	4.57 ± 0.45	NS
WBC ($\times 10^{9}$/L)	7.01 ± 1.90	6.87 ± 2.28	NS	6.55 ± 1.92	7.03 ± 2.11	NS
Creatinine (umol/L)	85.05 ± 19.88	84.84 ± 20.10	NS	83.42 ± 19.87	75.47 ± 18.60	<0.01
ALT (IU/L)	36.89 ± 7.01	36.63 ± 9.56	NS	41.00 ± 15.46	36.95 ± 7.18	NS

Table 5. Laboratory test results (mean ± SD) of Group B patients. Weeks 3, 4 and 5 were the washout period. NS stands for non-significant

	On Placebo			On ARND		
	Baseline	End of 2nd week	p-value	End of 5th week	End of 7th week	p-value
RBC ($\times 10^{12}$/L)	4.76 ± 0.39	4.73 ± 0.34	NS	4.71 ± 0.40	4.69 ± 0.27	NS
WBC ($\times 10^{9}$/L)	6.73 ± 1.43	6.06 ± 1.57	NS	6.34 ± 1.46	6.53 ± 1.80	NS
Creatinine (umol/L)	91.00 ± 13.66	89.13 ± 11.82	NS	89.67 ± 15.61	82.67 ± 12.58	NS
ALT (IU/L)	37.80 ± 8.80	38.93 ± 12.36	NS	39.87 ± 14.42	38.33 ± 8.67	NS

DOI: 10.1002/ptr

Table 6. Changes in the ChQOL scores (mean ± SD) of patients in Group A (n = 20). Weeks 3, 4 and 5 were the washout period. NS stands for non-significant

ChQOL Facets (F) & Domains (D)	On ARND			On Placebo		
	Baseline	End of 2nd Week	p-value	End of 5th Week	End of 7th Week	p-value
Complexion (F1)	35.62 ± 19.57	45.63 ± 16.61	<0.05	47.18 ± 17.96	47.81 ± 15.61	NS
Sleep (F2)	47.50 ± 16.68	58.33 ± 19.86	<0.05	54.17 ± 16.33	55.83 ± 15.32	NS
Consciousness (F6)	66.25 ± 14.43	62.08 ± 15.87	NS	62.92 ± 14.93	55.83 ± 17.33	<0.05
Spirit of Eye (F8)	45.00 ± 25.13	50.00 ± 23.99	NS	55.63 ± 20.46	47.50 ± 19.27	<0.05
Spirit (D2)	55.88 ± 14.36	56.27 ± 18.32	NS	58.60 ± 15.82	53.71 ± 14.67	<0.05

Table 7. Changes in the ChQOL scores (mean ± SD) of patients in Group B (n = 15). Weeks 3, 4 and 5 were the washout period. NS stands for non-significant

ChQOL Facets (F) & Domains (D)	On Placebo			On ARND		
	Baseline	End of 2nd Week	p-value	End of 5th Week	End of 7th Week	p-value
Appetite & Digestion (F4)	62.92 ± 11.20	67.08 ± 14.84	NS	60.42 ± 11.97	67.08 ± 16.10	0.01
Joy (F10)	54.58 ± 20.93	50.83 ± 17.66	NS	51.67 ± 20.79	57.08 ± 23.37	<0.05

Table 8. Changes in the ChQOL scores (mean ± SD) of 35 patients in both groups. Weeks 3, 4 and 5 were the washout period

ChQOL Facets (F) & Domains (D)	Pre-treatment with ARND	Post-treatment with ARND	p-value
Complexion (F1)	42.14 ± 19.19	47.85 ± 17.41	<0.05
Sleep (F2)	49.52 ± 15.25	56.90 ± 17.33	<0.01
Physical Form (D1)	52.27 ± 10.47	56.60 ± 13.21	<0.05

Quality of life assessment

Significant changes in the scores of different facets and domains of patients of Group A, Group B and the combined cohort were observed. For Group A (n = 20), significant improvements in complexion and sleep ($P < 0.05$ for both) were observed after treatment with ARND, but no such changes were observed after applying placebo when the scores were compared with those after the washout period. Furthermore, significant deteriorations of consciousness and spirit of the eye ($P < 0.05$ for both) leading to a significant decrease in the score of the domain of spirit ($P < 0.05$) were observed for Group A patients after applying placebo, but no such changes were observed after treatment with ARND.

For Group B (n = 15), no significant improvement or deterioration in any facet or domain was observed when the patients applied placebo for the first two weeks. However, significant improvements in appetite and digestion ($P = 0.01$) as well as joy ($P < 0.05$) were observed at the end of treatment with ARND after the washout period. Table 6 shows the above-mentioned changes of Group A and Table 7 of Group B.

When the outcomes of two groups with the same treatments were combined, i.e., from 20 Group A patients on ARND for the first 2 weeks plus 15 Group B patients on ARND for the last 2 weeks and the same for those subjects on placebo, significant improvements in complexion ($P < 0.05$) and sleep ($P < 0.01$) were observed at the end of the ARND treatment period when compared with the total baseline level (level at 0 week for Group A plus that at the 5th week for Group B). No such changes were observed for the combined Group after the placebo period. Table 8 summarizes the observed results.

DISCUSSION

Patients with symptoms of PAR are often treated with antihistamines, decongestants or steroids, etc., either orally or in the form of nasal sprays. These treatments usually provide relief of symptoms, but adverse effects are not uncommon. Natural products – including Chinese herbal medicines – are becoming increasingly popular worldwide as complementary treatment for various diseases (WHO, 2002; NCCAM, 2003). In the practice of Chinese medicine, a number of Chinese medicinal materials (CMM) are used together to form a balanced formulation for providing the efficacy in treatment and prevention of disease processes (Zhang, 1990). As mentioned earlier, the use of CMM for the treatment of allergic rhinitis has previously shown success in such approach (Xue *et al.*, 2003; Brinkhaus *et al.*, 2004).

The challenge in the use of CMM is that one must ensure that safety is closely observed and efficacy is evidence-based. In the present study, no adverse effect was observed clinically as well as indicated by renal function, liver function and haematological tests (Tables 4 and 5) after treatment with ARND. As far as the evidence-based efficacy is concerned, the major focus of outcomes is the evaluation of the impact of PAR and its treatment with ARND on the clinical symptoms as

DOI: 10.1002/ptr

determined by the specialist in internal medicine, and QOL assessment guided by the Chinese medicine practitioner as patient reported outcomes. As indicated in both Tables 2 and 3, the patients' clinical condition improved after 2-week treatment with ARND. The relief of symptoms was less obvious after placebo for patients in both groups.

It has been recognized that AR symptoms can have detrimental effects on the physical, psychological, and social aspects of patients' living conditions and environment, and that a variety of pharmacological therapies with pharmaceutical drugs can significantly improve the HRQOL of patients with AR (Juniper, 1998a; 1998b). Some examples of clinical studies using generic or specific instruments for evaluation of HRQOL in AR have been mentioned in the literature (Blaiss, 1999; Thompson *et al.*, 2000). None of them addresses the concepts and practice of using CM, although a few studies of CM in the treatment of patients with AR employed the Rhinoconjunctivitis and Rhinitis Quality of Life Questionnaire (Xue *et al.*, 2003; Brinkhaus *et al.*, 2004). In the present study, a Chinese medicinal nasal drop was used for treatment of AR and the ChQOL instrument (modification of the HRQOL for use with the practice of Chinese medicine) was employed to assess the integrity of health well-being in terms of the patients' physical form, emotion, and interaction with nature and the society. As indicated in Table 6, complexion and sleep in Group A patients showed significant improvements after treatment with ARND. Improvements in appetite and digestion, and joy were observed in Group B patients after treatment with ARND as indicated in Table 7. However, no such changes were observed when patients of both groups were on placebo. In fact, consciousness and spirit of eye in Group A patients deteriorated significantly after applying placebo (Table 6), giving rise to a significant decrease in the spirit domain. As the content of the placebo was a mixture of two common Chinese herbs which have not been known to impose any adverse effect on patients with PAR, the deterioration in QOL could be directly related to the disease process of the patients without an effective treatment. Furthermore, when the QOL of patients in both groups were viewed as a whole, significant improvements in complexion and sleep were observed after treatment with ARND, leading to a significant increase in the physical form domain (Table 8). The diversity of different facets and domains showing improvements in patients of different groups may be associated with the difference in severity of symptoms in different patients. In conclusion, the present study shows that ARND may have therapeutic effect on PAR. It can relieve clinical symptoms in patients with PAR and improve their QOL. In addition, ChQOL may be a more suitable instrument for the evaluation of QOL in clinical studies with Chinese medicines.

Acknowledgements

This study was sponsored by Lai Sing Medicine Factory Limited (Lai's Medicine) and supported by Macau University of Science and Technology Foundation.

REFERENCES

Bergner M, Bobbit RA, Carter WB. 1981. The sickness impact profile: development and final revision of a health status measure. *Med Care* **9**: 787–805.

Blaiss MS. 1999. Quality of life in allergic rhinitis. *Annals of Allergy, Asthma & Immunology* **83**(5): 449–454.

Brinkhaus B, Hummelsberger J, Kohnen R, Seufert J, Hempen CH, Leonhardy H, Nogel R, Joos S, Hahn E, Schuppan D. 2004. Acupuncture and Chinese herbal medicine in the treatment of patients with seasonal allergic rhinitis: a randomized-controlled clinical trial. *Allergy* **59**(9): 953–960.

Evans R III. 1993. Epidemiology and natural history of asthma, allergic rhinitis and atopic dermatitis. In *Allergy: principles and practice*, Middleton E Jr, Reed CE, Ellis EF, Adkinson NR Jr, Yunging er JW, Busse WW (eds). CV Mosby: St Louis, MO; 1109–1136.

Juniper EF. 1998a. Impact of upper respiratory allergic diseases on quality of life. *J Allergy Clin Immunol* **101**(2 pt 2): S386–S391.

Juniper EF. 1998b. Rhinitis management: the patient's perspective. *Clin Exp Allergy* **28**(Suppl 6): 34–38.

Juniper EF, Guyatt GH. 1991. Development and testing of a new measure of health status for clinical trials in rhinocon-junctivitis. *Clin Exp Allergy* **21**: 77–83.

Leung KF, Liu FB, Zhao L, Fang JQ, Chan K, Lin LZ. 2005. Development and validation of the Chinese Quality of Life Instrument. *Health Qual Life Outcomes* **3**: 26–44

Meltzer EO, Tyrell RJ, Rich D, Wood CC. 1995. A pharmacologic continuum in the treatment of rhinorrhea: the clinician as economist. *J Allergy Clin Immunol* **95**(5 pt 2): 1147–1152.

NCCAM (National Center for Complementary and Alternative Medicine). http://nccam:nih.gov [16 July 2003].

Reilly MC, Zbrozek AS, Dukes EM. 1993. The validity and reproducibility of a work productivity and activity impairment instrument. *PharmacoEconomics* **4**(5): 353–365.

Reilly MC, Tanner A, Meltzer EO. 1996. Work, classroom, and activity impairment instruments. *Clin Drug Invest* **11**(5): 278–288.

Sibbald B, Rink E. 1991. Epidemiology of seasonal and perennial rhinitis: clinical presentation and medical history. *Thorax* **46**: 895–901.

Thompson AK, Juniper E, Meltzer EO. 2000. Quality of life in patients with allergic rhinitis. *Annals of Allergy, Asthma & Immunology* **85**(5): 338–347.

Ventura MT, Piccinni T, Matino MG, Giuliano G, Corato Rdi, Napoli Di, Tursi A. 2001. Retrospective study on flutiocasone propionate aqueous nasal spray efficacy in patients with allergic rhinitis : evaluation of clinical and laboratory parameters. *Allergy* **56**: 29–34.

Ware JE, Sherbourne CD. 1992. The MOS 36-item short-form health survey (SF-36): I. Conceptual framework and item selection. *Med Care* **30**: 473–483.

Ware JE, Kosinski M, Keller SD. 1996. A 12-item short form health survey construction of scales and preliminary tests of reliability and validity. *Med Care* **34**: 220–233.

WHO Traditional Medicine Strategy 2002–2005. World Health Organization 2002, 1–66. http://www.who.int/medicines/library/trm/trm_strat_eng.pdf [16 July 2003].

Xue CC, Thien FC, Zhang JJ, Da Costa C, Li CG. 2003. Treatment for seasonal allergic rhinitis by Chinese herbal medicine: a randomized placebo controlled trial. *Altern Ther Health Med* **9**(5): 80–87.

Zhang EQ (ed.). 1990. Formation of a prescription. In *Prescriptions of Traditional Chinese Medicine*. Publishing House of Shanghai College of Traditional Chinese Medicine: Shanghai; 10–12.

Zhao L. Chan K.2005. Building a bridge for integrating Chinese medicine into conventional healthcare: Observations drawn from the Chinese Quality of Life Instrument development. *Am J Chinese Med* **33**: 897–902.