

## RESEARCH ARTICLE

## Effect of Traditional Chinese Medicine plus narrow-band medium-wave ultraviolet B radiation on moderate-to-severe psoriasis vulgaris in a case series

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of Traditional Chinese Medicine (TCM) therapy combined with ultraviolet B light therapy in the treatment of moderate-to-severe psoriasis.

**METHODS:** Patients with moderate-to-severe psoriasis (skin lesion area > 10% of the body surface area) for 2 consecutive years were treated with TCM (oral and external use of herbal medicines, acupuncture, and herbal bathing) and narrow-band medium-wave ultraviolet B light treatment for 12 weeks. The treatment effect was evaluated based on the Psoriasis Area Severity Index (PASI), the achievement of a 50% reduction in the PASI (PASI50), the achievement of a 75% reduction in the PASI (PASI75), pruritus score, Dermatology Life Quality Index, and safety.

**RESULTS:** A total of 95 outpatients were enrolled, and 92 subjects (96.8%) completed the 12-week treatment course. At baseline, the average proportion of the body surface area covered by skin lesions was 12.4%, and the average PASI was 17.7. All patients had previously been treated with conventional medicine (89.1% of patients received ultraviolet light treatment, 50.0% received glucocorticoids, and 21.7% received acitretin). After the 12-week treatment course, 22 patients (23.9%) achieved PASI75, and 43 (46.7%) achieved PASI50. The post-treatment pruritus score and Dermatology Life Quality Index of all treated patients were significantly lower than the respective baseline values ( $P < 0.0001$ ). No adverse effects were detected by the monitoring of blood, urine, stools, liver and kidney function, and echocardiography.

### Abstract

**OBJECTIVE:** To investigate the efficacy and safety

**CONCLUSION:** Comprehensive therapy comprising TCM therapy combined with ultraviolet B light therapy achieved good outcomes for patients with moderate-to-severe psoriasis.

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**Keywords:** Psoriasis; Ultraviolet therapy; Medicine, Chinese Traditional; Quality of life

## INTRODUCTION

Psoriasis is a chronic recurrent inflammatory skin disease currently characterized by the highest incidence and curability difficulty in the field of dermatology. The incidence of psoriasis varies from 0.1% to 3.0% in the general population.<sup>1</sup> In 2016, the World Health Organization stated that the "Prevalence of psoriasis, announced by various countries, ranges between 0.09% and 11.43%", with a gradually increasing trend.<sup>2</sup> Psoriasis is characterized by frequent episodes of relapse. Furthermore, approximately 17% of all patients with psoriasis have moderate-to-severe psoriasis.<sup>3</sup> Moderate-to-severe psoriasis features refractory skin lesions, long disease duration, and no possibility of lesion regression, which seriously affects the quality of life.

The diagnostic criteria for moderate-to-severe psoriasis include a body surface area involvement of > 10%, Psoriasis Area and Severity Index of > 10, or Dermatology Life Quality Index (DLQI) > 10, which are based on the consensus of 19 dermatologists from European countries after four rounds of Delphi procedures.<sup>4</sup> Conventional medical treatment of moderate-to-severe psoriasis mostly involves the administration of acitretin,<sup>5</sup> methotrexate,<sup>6</sup> cyclosporine,<sup>7</sup> light therapy or ultraviolet B (UVB) combined treatment.<sup>4,8</sup> Although these treatments have proven efficacy, a considerable number of patients still show a poor early-phase response. Moreover, the majority of these conventional treatments have adverse effects that impair the functions of organs (such as the liver and kidney) and lead to relapse.<sup>9-15</sup> In comparison with conventional medicine, TCM has less adverse effects. Therefore, psoriasis has become one of the diseases commonly treated with TCM by dermatologists in TCM hospitals.<sup>16</sup> TCM therapy usually includes the oral administration and topical application of herbal extracts, acupuncture, and herbal bathing therapy.

Narrow-band medium-wave UVB (NB-UVB) has strong permeability, and has become a more popular type of light therapy in recent years. NB-UVB is effective for psoriasis, and has low phototoxicity.<sup>17</sup> The risk-return ratio suggests that NB-UVB is safe and effective for moderate-to-severe psoriasis,<sup>18</sup> and so NB-UVB light therapy has become a first-line treatment option for psoriasis.<sup>19</sup> Long-term treatment of

moderate-to-severe psoriasis requires a personalized approach. Combined therapy is commonly used not only to alleviate the cumulative toxicity of anti-psoriasis treatments,<sup>20</sup> but also to optimize the risk-return ratio of treatment, such as via the use of UVB combination therapy.<sup>5,21</sup>

A systemic analysis of the accumulated experience of 16 prestigious TCM physicians from Beijing found that the major focus of the treatment of severe psoriasis is on the "blood" (in the broad TCM concept), and that psoriasis falls into three TCM syndrome types: blood heat, blood dryness, and blood stasis.<sup>22</sup> Patients with refractory moderate-to-severe psoriasis mainly have blood dryness and blood stasis due to long-term skin lesions.<sup>23-25</sup> It is proposed that psoriasis recurrence causes blood heat to gradually evolve into blood dryness or blood stasis.<sup>26</sup> Therefore, the present case series study evaluated the efficacy and safety of multipronged TCM therapy combined with NB-UVB therapy for moderate-to-severe psoriasis that was unresponsive to conventional medical treatment.

## MATERIALS AND METHODS

### *Design*

Prospective case series study.

### *Ethical policy*

This research was undertaken at Beijing TCM Hospital with the approval of the Ethics Committee (application No. 201001-2). The trial was registered in the China Clinical Trials Research Center (registration No. ChiCTR-TRC-00000311). All enrolled patients provided written informed consent for study inclusion.

### *Case sources and inclusion and exclusion criteria*

The enrolled subjects were psoriatic outpatients in the Department of Dermatology, Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University.

The inclusion criteria were as follows. (a) Patients who satisfied the conventional medicine diagnostic criteria for psoriasis vulgaris in accordance with the Chinese Medical Association: Clinical Diagnosis and Treatment Guidelines--Volume of Skin Diseases and Sexually Transmitted Diseases<sup>27</sup> and Chinese Clinical Dermatology.<sup>28</sup> (b) Skin lesions covering > 10% of the body surface area for 2 consecutive years or longer. (c) Patients who satisfied the TCM diagnostic criteria for blood stasis or blood dryness in accordance with the Chinese Medicine Dermatology,<sup>29</sup> Syndrome Diagnosis and Treatment Criteria of Traditional Chinese Medicine<sup>30</sup> and Clinical Research Guidelines for New Drugs of Traditional Chinese Medicine,<sup>31</sup> in combination with our accumulated experience and combined knowledge on TCM syndrome differentiation treatment of psoriasis. The two main TCM syndromes associated with

psoriasis are blood dryness and blood stasis. The major symptoms of blood dryness are subsidence of the original skin lesions, resulting in a pink skin color, while the minor symptoms are a pale tongue with little or thin white tongue coating, a slow or weak pulse, and a dry mouth and throat. The major symptoms of blood stasis are hypertrophy and infiltration of enduring skin lesions, resulting in dark red skin color, while the minor symptoms are dark purple coloration, petechiae or ecchymosis of the tongue, a slow or weak pulse, and possible dysmenorrhea in women. The TCM syndrome was diagnosed based on the presence of one major symptom and one minor symptom. (d) Age 18-65 years. (e) Voluntary provision of written informed consent.

The exclusion criteria were: (a) pregnancy or lactation; (b) oral intake of glucocorticoid and/or immunosuppressive drugs, and retinoic acid drugs; (c) concomitant severe primary disease and/or mental illness.

### **Treatments**

Patients were treated with multipronged TCM therapy combined with systemic NB-UVB radiation treatment. The 12-week comprehensive treatment course was started after preexisting treatment had been stopped for 1 month.

different prescriptions were chosen in accordance with the TCM syndrome differentiation. Patients with blood dryness were administered Blood Nourishing and Toxin Removing Decoction. Patients with blood stasis were administered Blood Activating and Toxin Removing Decoction. These prescriptions were prepared by the hospital pharmacy using a standard procedure into TCM decoctions (200 mL/bottle). The decoction was orally administered twice daily (half an hour after the morning meal and the evening meal, 100 mL each time).

Scutellaria-Phellodendron ointment (approval number Beijing Self-made Medicine Z20053387) was made by the Beijing Hospital of Traditional Chinese Medicine. Patients in the treatment group topically applied Scutellaria-Phellodendron ointment twice daily (in the morning and in the evening). The ointment was evenly applied to the affected areas.

Angelica-Caulis lotion was prepared as follows. The herbs were extracted in about 3 L of simmering water for 25 min, and the supernatant (2.5 L) was collected as the first decoction. After adding an additional 3 L of water, the herbs were extracted for another 20 min as the second decoction (about 2.5 L). The two decoctions were pooled, filtered, and diluted in water (1:10) for the purpose of bathing. The decoction was prepared in the hospital decoction room. The medicated bath container was an oval-shaped wooden bathtub. A barrel-shaped plastic film was placed inside the bathtub, with the edge of the film covering the upper edge of the bathtub. The bath was filled with the decoction to the shoulder level of patients in the bathtub. All pa-

tients bathed in the decoction at 38-39 °C for 20 min every day. During menstruation, a hydrophatic compress was used instead of the medicated bath.

Basic acupuncture points were: Quchi (LI 11, bilateral), Hegu (LI 4, bilateral), Xuehai (SP 10, bilateral), Sanyinjiao (SP 6, bilateral), Zusanli (ST 36, bilateral), Baihui (GV 20, plus/min). In addition, patients with blood dryness received acupuncture at Yinlingquan (SP9, bilateral) and Neiguan (PC 6, bilateral), while those with blood stasis received acupuncture at Tianshu (ST 25, bilateral) and Qihai (CV 6). Acupuncture was performed three times per week for 30 min each time (without electro-acupuncture) using reinforcing and reducing methods with a focus on lifting, insertion, and twisting. The acupuncture was performed after bathing to avoid possible infection.

Whole body NB-UVB phototherapy (German Warman UV-7100L, 311 nm NB-UVB) was performed three times per week. As Chinese people generally have Type III and Type IV skin, the initial dose exposure was set for each individual patient in accordance with the sub-erythema dose and the patient's tolerance to ultraviolet radiation. The dose was subsequently increased by 0.1 J/cm<sup>2</sup> each time until either erythema appeared or the rash substantially dissipated. When the total dose reached 1.3 J/cm<sup>2</sup>, the dose was maintained at this level for several treatments before the dose was adjusted.

Oral and external TCM treatments were applied in the morning and evening at home each day. NB-UVB therapy, bathing, and acupuncture were carried out in the hospital (in that order) every other day, three times per week. The treatment course was 12 weeks. During the treatment period, patients were prohibited from eating fish, shrimp, beef, lamb, pepper, and other irritating foods. The use of glucocorticoids, retinoic acid, immunosuppressive agents, and biological agents was also prohibited during the treatment period.

### **Evaluation of curative effect**

The PASI<sup>32</sup> was evaluated at baseline and at 2, 4, 6, 8, 10, and 12 weeks after treatment commencement. The PASI score was based on the lesion area, erythema, infiltration, desquamation, and other indicators. Patients were assessed to determine whether they achieved a 50% reduction in the PASI (PASI50), a 75% reduction in the PASI (PASI75), and a 95% reduction in the PASI (PASI95).

The pruritus score was assessed in accordance with the Clinical Research Guidelines for New Drugs of Traditional Chinese Medicine.<sup>33</sup> The degree of pruritus was categorized as: none (score 0), mild occasional pruritus without the need for treatment and no adverse effect on work and life (score 3), moderate paroxysmal pruritus that required treatment and had a slight adverse effect on sleep and work (score 5), or severe pruritus that had serious adverse effects on sleep, work and life (score 7).

The quality of life was assessed using the DQLI, which was first applied for clinical research in 1994 and has since been adopted for use worldwide.

The safety of treatment was also evaluated. At each follow-up visit, the physicians asked the patients whether they had experienced any adverse reactions, and performed physical examinations to detect adverse reactions. Safety testing was carried out prior to treatment and at the end of the 12-week treatment course, including biochemical analysis of blood, urine, and stools (mainly focusing on the assessment of hepatic and renal function), as well as electrocardiography.

### Data management and analysis

Unified Case Report Forms were filled out by physicians at the Department of Dermatology. Each patient was followed up by a designated physician. The data entry was performed by one person. The database was a clinical research data acquisition and management system developed by Nanjing University of Traditional Chinese Medicine Hospital and Nanjing Haitai Information Technology Co., Ltd. (<http://www.njecd.com/>). All data were analyzed with SPSS for Windows, version 17.0 (SPSS Inc., Chicago, IL, USA). *T*-tests and  $\chi^2$  tests were conducted to evaluate the differences between groups.  $P < 0.05$  was considered statistically significant.

## RESULTS

### Characteristics of included patients

From August 2010 to December 2013, a total of 95 outpatients were treated for intractable psoriasis at the Department of Dermatology, Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University. Three patients were excluded from the present study (one due to stomach discomfort, and the other two for unknown reasons). The remaining 92 patients (96.8%) completed the 12-week TCM comprehensive treatment course. The male: female ratio was 5.1:1. The average age was ( $43 \pm 13$ ) years, and the average disease duration was ( $17 \pm 10$ ) years. The incidence of a family history of psoriasis was 32.6%, while 22.8% of patients had fatty liver, diabetes mellitus, hypertension, hyperthyroidism, or other diseases. All en-

Table 1 Characteristics of Included Patients

Item	Indicator	Data
Age (years)	Mean $\pm$ SD	43 $\pm$ 13
	Min-Max	21.00-65.00
Gender [ <i>n</i> (%)]	Male	77(83.70)
	Female	15(16.30)
Family history of psoriasis [ <i>n</i> (%)]	No	62(67.39)
	Yes	30(32.61)
Other complications [ <i>n</i> (%)]	No	71(77.17)
	Yes	21(22.83)
Course of disease (years)	Mean $\pm$ SD	17 $\pm$ 10
	Min-Max	2.00-40.00
Recipients of previous medical treatment [ <i>n</i> (%)]	Phototherapy	82(89.13)
	Glucocorticoid	46(50.00)
	Acitretin	20(21.74)
Area (BSA, %)	Mean $\pm$ SD	12 $\pm$ 3
	Min-Max	10.00-19.00
PASI baseline	Mean $\pm$ SD	18 $\pm$ 10

Notes: SD: standard deviation; PASI: Psoriasis Area Severity Index; BSA: body surface area

rolled patients had previously received conventional medical treatment, including phototherapy (89.1%), glucocorticoid administration (50.0%), or acitretin treatment (21.7%). All patients in the treatment group satisfied the diagnostic criteria for moderate-to-severe psoriasis (Table 1).

### Clinical efficacy

After the 12-week treatment course comprising multipronged TCM therapy combined with NB-UVB treatment, the PASI scores were significantly lowered compared with baseline. In week 12, 46.74% had achieved PASI50, 23.91% had achieved PASI75, and 7.61% had achieved PASI95 (Table 2, Figure 1). Compared with baseline values, there were significant post-treatment decreases in the pruritus score ( $5.72 \pm 1.59$  versus  $3.28 \pm 2.65$ ;  $Z = -5.730$ ,  $P < 0.001$ ) and the DQ-LI ( $19.43 \pm 5.15$  versus  $12.99 \pm 4.75$ ;  $t = 12.08$ ,  $P < 0.001$ ).

Table 2 PASI Scores before and after TCM multipronged therapy combined with nb-uvb treatment

Items	Week 0	Week 4	Week 8	Week 12
PASI score (mean $\pm$ SD)	18 $\pm$ 10	13 $\pm$ 9	11 $\pm$ 10	10 $\pm$ 10
PASI mean improvement (%)		26.95	35.03	43.28
PASI95 [ <i>n</i> (%)]		1(1.09)	2(2.17)	7(7.61)
PASI75 [ <i>n</i> (%)]		5(5.43)	14(15.22)	22(23.91)
PASI50 [ <i>n</i> (%)]		20(21.74)	35(38.04)	43(46.74)

Notes: SD: standard deviation; PASI: Psoriasis Area Severity Index; TCM: traditional Chinese medicine; NB-UVB: narrow-band medium-wave ultraviolet B radiation; PASI95: achievement of a 95% reduction in the PASI; PASI75: achievement of a 75% reduction in the PASI; PASI50: achievement of a 50% reduction in the PASI.  $t = 5.247$ ,  $P < 0.01$  for the comparison of PASI score before treatment versus after treatment.

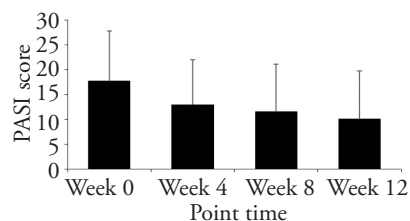


Figure 1 PASI score changes over time  
PASI: Psoriasis Area Severity Index.

Some adverse events were observed during the study period. One patient experienced pruritus after the topical application of a medicine, but was able to tolerate this medicine in oral form and completed the whole treatment course. Three patients experienced stomach discomfort; one of these patients was withdrawn from the study, while the symptoms resolved in the other two patients, and so they remained in the study. Two patients experienced pruritus that resolved after the phototherapy dose was reduced. Thus, the incidence of adverse events was 6.52%. There were no abnormalities detected in the examinations of blood, urine, stools, and electrocardiography.

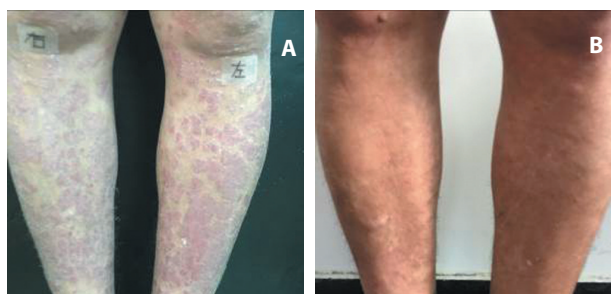


Figure 2 Photographs of a patient with moderate-to-severe psoriasis

A: Plaque-type psoriasis lesions on the lower limbs at baseline. B: Complete clearance of the lesions at 12 weeks after treatment commencement.

## DISCUSSION

Treatment comprising multipronged TCM therapy plus NB-UVB for 12 weeks achieved a good curative effect in patients with moderate-to-severe psoriasis. PASI95 was achieved by 7.61% of patients, 23.91% achieved PASI75, and 46.74% achieved PASI50. Compared with baseline values, the pruritus score was significantly decreased and the DQLI was significantly improved after treatment. No serious adverse effects were observed.

In conventional medicine, treatment options for refractory psoriasis include methotrexate, cyclosporine, acitretin, phototherapy, and new biological agents. However, the application of these treatments are often associated with severe adverse effects such as hepatotoxicity, myelosuppression (methotrexate), renal failure (cyclosporine), hyperlipidemia (cyclosporine and acitretin), and skin cancer (psoralen plus ultraviolet A therapy), making it difficult to control the treatment procedure.<sup>6</sup> Previous studies have reported either unsatisfac-

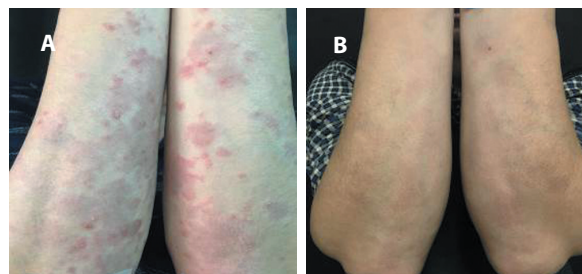


Figure 3 Photographs of a patient with moderate-to-severe psoriasis

A: Plaque-type psoriasis lesions over the upper limbs at baseline. B: Complete clearance of lesions at 12 weeks after the commencement of treatment.

tory outcomes or severe adverse effects due to the use of conventional medicines, including acitretin,<sup>13</sup> methotrexate,<sup>10,12</sup> and cyclosporine.<sup>11,14</sup>

Compared with the outcomes of conventional treatment, the treatment strategy used in the present study achieved similar or slightly worse outcomes. However, all patients enrolled in the present study had previously been treated with conventional medicine, and their conditions had relapsed. Therefore, it is expected that this multipronged TCM therapy combined with



Figure 4 Photographs of a patient with moderate-to-severe psoriasis

A: Plaque-type psoriasis lesions over the lower limbs at baseline. B: Complete clearance of lesions at 12 weeks after treatment commencement.

NB-UVB treatment may achieve better efficacy when used in naive patients during a longer treatment period. Moreover, the present treatment strategy had negligible adverse effects; this makes it more suitable than conventional medical treatment for the long-term continuous treatment of moderate-to-severe psoriasis, as the long-term application of conventional medicines raises serious safety issues that restrict the scope and time of application.<sup>34</sup> Although a short-term curative effect is achieved by the administration of biological drugs available for the treatment of moderate-to-severe psoriasis, such as Infliximab, Etanercept, and Adalimumab,<sup>35-37</sup> the clinical application of these agents is restricted by their high cost, low long-term therapeutic efficacy, and serious adverse effects.<sup>38</sup>

The main TCM herbs included in the prescription for oral administration have blood nourishing and toxin removing effects to improve the overall condition of the patients. Modern pharmacological studies have shown that the blood nourishing and toxin removing deco-

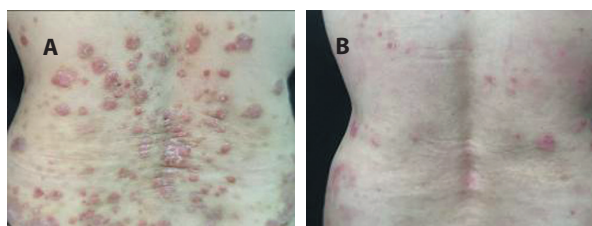


Figure 5 Photographs of a patient with moderate-to-severe psoriasis

A: plaque-type psoriasis lesions over the back at baseline; B: complete clearance of the lesions at 12 weeks after treatment commencement.



Figure 6 Photographs of a patient with moderate-to-severe psoriasis

A: plaque-type psoriasis lesions over the lower limbs at baseline; B: thinning of the skin rash and characteristic central clearing of the lesions at 12 weeks after treatment commencement.

tion significantly reduces serum levels of interleukin-6, interferon- $\gamma$  and tumor necrosis factor- $\alpha$  in patients with psoriasis, so that the immune regulation becomes normal.<sup>39</sup> This is because the herbs promote blood circulation and remove stasis, dilate blood vessels, improve the microcirculation, adjust the immune function, and regulate the metabolism of skin cells. Therefore, these herbs adjust the status of immune regulation in patients with psoriasis and improve psoriasis microcirculation, thereby promoting normal differentiation of psoriasis skin lesions and correcting keratinocyte hyperkeratosis.<sup>40</sup>

The skin is the pathogenic site of psoriasis, and so external treatment is an important treatment method for this disease. It is believed that keeping warm can improve the blood circulation and suppress inflammation. Thus, a medicated bath softens and removes the squamation of psoriasis. TCM medicated fumigation therapy not only regulates the abnormal keratosis of epithelial cells at the psoriasis lesion site, but also speeds up the recovery of cell function.<sup>41</sup> The main herbs in the Angelica-Caulis lotion used in the present study are Danggui (*Radix Angelicae Sinensis*), Jixueteng (*Caulis Spatholobi*), and Shouwuteng (*Caulis Polygoni Multiflori*), which nourish and activate the blood. The other herbs in the decoction dispel wind, remove dampness and toxins, and relieve itching.

The Scutellaria-Phellodendron ointment used in the present study clears heat, detoxifies, and reduces swelling pain. This ointment contains "Huangqinqing", which reduces neutrophil chemotaxis of leukotrienes, and inhibits fibroblast cell cycles due to the suppressed proliferation effect.<sup>42</sup> Scutellaria-Phellodendron ointment also contains Phellodendron amurense, which in-

hibits the proliferation of fibroblasts, modulates the intracellular free calcium concentration in fibroblasts, reduces the intima potential of fibroblasts, leads to mitochondrial calcium outflux, and interferes with the pathogenesis of psoriasis.<sup>43</sup> Animal experiments have proven that Scutellaria-Phellodendron ointment significantly inhibits the vaginal epithelium mitosis in mice, and significantly contributes to the formation of a granular layer in mouse tail scale epidermis.<sup>44</sup>

Many clinical reports demonstrate that acupuncture is an effective treatment for psoriasis. Acupuncture treatment is systematic and achieves marked long-term effects in the treatment of psoriasis, including extension of the recurrence onset time and reduction of the recurrence rate.<sup>45</sup>

NB-UVB radiation treatment has increasingly been used due to its good curative effects for psoriasis and other skin diseases, and its relatively low toxicity.<sup>46</sup> Study showed that NB-UVB phototherapy for patients with psoriasis was an essential method for decreasing PASI scores.<sup>47</sup> The good efficacy of NB-UVB treatment for psoriasis is attributed to the induction of apoptosis of T lymphocytes and Langerhans cells, and inhibition of the release and transport of proinflammatory cytokines.<sup>48</sup>

In conclusion, typical multipronged TCM therapy (comprising the administration of herbs orally, topically, and via bathing) plus NB-UVB radiation treatment for moderate-to-severe psoriasis is a safe and effective strategy that is easily accepted by patients. The present findings are encouraging; however, there were no follow-up visits after the treatment ended, and the treatment program is relatively complex and has some technical requirements. Our next step is to perform a study that includes a control group and a simplified treatment procedure.

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