# Research Snapshots

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## A RANDOMIZED CONTROLLED SINGLE-BLIND CLINICAL TRIAL ON 84 OUTPATIENTS WITH PSORIASIS VULGARIS BY AURICULAR THERAPY COMBINED WITH OPTIMIZED YINXIELING FORMULA (银屑灵优化方）

**OBJECTIVE:** To evaluate the effect of auricular therapy combined with optimised *Yinxieling* Formula（银屑灵优化方）on psoriasis vulgaris.

METHOD: This was a randomised, controlled, single-blind clinical trial conducted in Guangzhou, China. Eighty-four outpatients with psoriasis vulgaris were randomised to a treatment group (43 cases treated by auricular therapy combined with optimised *Yinxieling* formula) and a control group (41 cases treated by optimised *Yinxieling* formula alone). The treatment duration for both groups was eight weeks. Auricular therapy comprised of blood-letting puncture of the auricular points on the back of ear and vaccaria seeds pressure on Lung (CO 14), Liver (CO 12), *Shenmen* (TF 4), endocrine (CO 18), and *Pizhixia* (AT 4). Each ear was treated every other week for eight weeks in total. Both groups were treated with optimised *Yinxieling* formula decoction, which was a hospital preparation. The formula consisted of *Radix Paeoniae Rubra* (*Chi Shao*), *Rhizoma Curcumae* (*E Zhu*), Sarcandra (*Zhong Jie Feng*), *Radix glycytthizae* (*Gan Cao*), *Fructus Mume* (*Wu Mei*), *Radix Arnebiae* (*Zi Cao*), and *Rhizoma Smilacis Glabrae* (*Tu Fu Ling*). The outcome measure was Psoriasis Area and Severity Index (PASI) reduction rate, PASI score, Visual Analogue Scale (VAS) to evaluate itch severity, Dermatology Life Quality Index (DLQI), Self-rating Depression Scale (SDS), and Self-rating Anxiety Scale (SAS).

**RESULTS:** The PASI reduction rate in the treatment group was superior to the control group (74.4% vs 36.6%; $p < 0.01$). The PASI score was lower in the treatment group compared with the control group ($p < 0.01$).There were no significant differences between the two groups in DLQI, SDS, SAS and VAS ($p > 0.05$). No obvious adverse advents were found in either group.

**CONCLUSION:** Auricular therapy combined with optimised *Yinxieling* formula had a superior effect compared with optimised *Yinxieling* formula alone, with no serious adverse effects.

**COMMENTS:** The study introduced an adjunct, non-pharmacological therapy for psoriasis vulgaris patients. Additional auricular therapy appears to provide significant advantage to herbal medicine treatment alone. The study design was reasonable. Though blinding of participants and practitioners was impossible, blinding of outcome assessors was ensured. However, the study could not confirm whether the therapy has definite therapeutic effects or just a placebo effect. Further studies comparing auricular therapy and placebo should be conducted.

*Lu CJ, Xiang Y, Xie XL, Xuan ML, He ZH. A randomized controlled single-blind clinical trial on 84 outpatients with psoriasis vulgaris by auricular therapy combined with optimized Yinxieling Formula. Chin J Integr Med. 2012 Mar;18(3):186–91.*

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## BU-FEI YI-SHEN GRANULE COMBINED WITH ACUPOINT STICKING THERAPY IN PATIENTS WITH STABLE CHRONIC OBSTRUCTIVE PULMONARY DISEASE: A RANDOMIZED, DOUBLE-BLIND, DOUBLE-DUMMY, ACTIVE-CONTROLLED, 4-CENTER STUDY

**OBJECTIVE:** This study aimed to access the efficacy and safety of the *Bu-Fei Yi-Shen* granule combined with *Shu-fei Tie* acupoint sticking therapy, a treatment externally applying herbal paste to acupoints, in patients with stable Chronic Obstructive Pulmonary Disease (COPD).

**METHOD:** This study was designed as a multi-centre, randomised, double-blind, double-dummy, active-controlled trial in stable COPD patients. Two hundred and forty-four patients were randomly allocated to two groups. The trial group were given *Bu-Fei Yi-Qi* granule combined with *Shu-Fei*

*Tie* acupoint sticking therapy and oral placebo sustained-release theophylline. The control group were treated with oral sustained-release theophylline, which is standard, effective and well-tolerated in the long term treatment of stable COPD, and placebo *Bu-Fei Yi-Shen* granule combined with placebo *Shu-Fei Tie* acupoint sticking therapy. In both groups, *Bu-Fei Yi-Shen* granule and theophylline (or their placebos) were given twice daily for four months; the acupoint sticking therapy (or its placebo) was applied with 6–12 hour each patching time weekly for two months. Patients were followed up at six months after the end of the treatment. *Bu-Fei Yi-Shen* granule consisted of *renshen* (*Radix Ginseng*), 9 g; *huangqi* (*Radix Astragali Membranaceus*), 15 g; *gouqizi* (*Fructus Lycii*), 12 g; *diyu* (*Radix Sanguisorbae Officinalis*), 12 g; *wuweizi* (*Fructus Schisandrae Chinensis*), 9 g; *yinyanghuo* (*Herba Epimedii*), 9 g; *zisuzi* (*Fructus Perialle Frutescentis*), 9 g.

*Shu-fei Tie* plaster consisted of *baijiezi* (*Semen Sinapsis Albae*), 10 g; *yanhusuo* (*Rhizoma Corydalis Yanhusuo*), 5 g; *ganjiang* (*Rhizoma Zingiberis Officinalis*), 5 g; *xixin* (*Herba Cum Radice Asari*), 5 g; *yuanhua* (*Flos Daphnes Genkwa*), 10 g.

**OUTCOME:** The primary outcome measures were frequency and duration of acute exacerbation during the 10-month study. The secondary outcome measures included lung function, clinical symptoms, dyspnea grade, quality of life, six-minute walking distance (6MWD), and the adverse events (AE).

**RESULTS:** 221 patients completed the study (trial: $n$ = 112; control: $n$ = 109). No significant differences were observed between these two groups at baseline. The study showed that in the trial group the frequency and duration of acute exacerbation were significantly shortened ($p < 0.05$). All other outcome measures also significantly improved when compared with those in the control group. There was no statistical difference between two groups in the lung function. Ten adverse events were recorded in the trial group, three of which led to the patient's withdrawal. There were eight cases with adverse events in the control group.

**CONCLUSION:** Patients with stable COPD benefited more from the therapy of *Bu-Fei Yi-Shen* granule combined with acupoint sticking. Further studies are required to determine the responsive patient population as well as dosing regimen and therapy duration for this approach.

**COMMENT:** The authors acknowledged the limitation in the design, including neither single *Bu-Fei Yi-Shen* granule group nor single acupoint sticking group was assessed. Consequently, it is impossible to determine the contribution of *Bu-Fei Yi-Shen* granule and acupoint sticking therapy, respectively. In addition, the duration of the whole study might not have been long enough to reflect the change in lung function. Furthermore, the SD and 95% CI were only presented in graphs; therefore, the absolute figures can only be estimated based on the graphs.

*Li JS, Li SY, Yu XQ, Xie Y, Wang MH, Li ZG, et al. Bu-Fei Yi-Shen granule combined with acupoint sticking therapy in patients with stable chronic obstructive pulmonary disease: a randomized, double-blind, double-dummy, active-controlled, 4-center study. J Ethnopharmacol 2012;141(2): 584–91.*

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