

**A pilot study comparing the clinical effects of Jia-Way Shiao-Yau san, a traditional Chinese herbal prescription, and a continuous combined hormone replacement therapy in postmenopausal women with climacteric symptoms.**

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**Abstract:**

*Objectives:* Interest in use of alternative remedies for managing menopausal symptoms is increasing exponentially during these years. Jia-Wey Shiao-Yau San (JWSYS), one of the traditional Chinese herbal prescriptions, is a famous herbal remedy used for the management of various menopausal-related symptoms. A randomized, controlled pilot study was performed to evaluate the clinical effects of JWSYS compared with those of a continuous combined hormone replacement therapy, Premelle<sup>®</sup>, on quality of life in non-hysterectomized postmenopausal women.

*Methods:* The present trial compared the effect of a 16-week treatment with JWSYS or HRT (Premelle<sup>®</sup>) in postmenopausal women with climacteric symptoms. The Greene Climacteric Scale was used to assess the clinical effects at baseline and after 16 weeks' treatment with either JWSYS or Premelle<sup>®</sup>. The physiological parameters, such as follicle-stimulating hormone and estradiol levels, were also recorded at the same time points.

*Results:* The results showed that JWSYS had a relatively lower discontinuation rate due to adverse effects, in particular the bleeding and breast tenderness. Both JWSYS and Premelle<sup>®</sup> effectively alleviated most of the menopausal symptoms with no significant differences between treatment groups, whereas the beneficial effects of JWSYS were not mediated by hormone replacement-like effects. Moreover, JWSYS showed a good compliance and safety without estrogenic effects and metabolic alterations.

*Conclusions:* It was suggested that JWSYS was a safe and efficacious therapy and might be an alternative choice for relief of climacteric symptoms in postmenopausal women. However, the exact efficacy and clinical roles of JWSYS have not been convincingly demonstrated in this study because of the blinding approach and some statistical concerns, and only the possibility of its efficacy has been raised. Therefore, a blinding trial with more patient numbers to evaluate the efficacy of JWSYS deserves further study.