

## CLINICAL STUDY

## Effect of Guizhi Gancao Longgu Muli Tang on sleep disturbances in menopausal women

Wang Zhipeng, Ke Deng, Huang Xiaoqin, Ding Yang, Wang Changsong

**Wang Zhipeng, Ke Deng, Huang Xiaoqin, Ding Yang,** Traditional Chinese Medicine Department of Internal Medicine, Zhongda Hospital affiliated to Southeast University, Nanjing 210009, China

**Wang Changsong,** Internal Medicine Department of Traditional Chinese Medicine, Medicine School of Southeast University, Nanjing 210009, China

**Huang Xiaoqin,** Outpatient Department, Hospital of Nanjing University of Posts and Telecommunications, Nanjing 210023, China

**Supported by** Science Project of Traditional Chinese Medicine Bureau in Jiangsu Province of China: Analysis on Differences of Platelet Protein Under Syndrome of Cold-phlegm Blocking Heart Vessel And Targeted Intervention Mechanism of Furostanol Saponins of *Allium Macrostemon Bunge* for Coronary Heart Disease (No. YB2015180); Chinese Medicine Teaching center of Southeast University

**Correspondence to: Prof. Wang Changsong,** Internal Medicine Department of Traditional Chinese Medicine, School of Medicine affiliated to Southeast University, Nanjing 210009, China. kingidoc@263.net

**Telephone:** +86-25-83272175; +86-13645188512

**Accepted:** April 30, 2016

### Abstract

**OBJECTIVE:** To evaluate the effect of Guizhi Gancao Longgu Muli Tang (GGLMT), a decoction prepared with herbal medicine of Traditional Chinese Medicine, on sleep disturbances in women with menopause.

**METHODS:** Totally 162 participants were recruited for the treatment of sleep difficulty from February, 2012 to December, 2014. Decoction of 200 mL was taken by every participant twice daily in half an hour after lunch and dinner during two weeks. Sleep quality was assessed by Pittsburgh sleep quality

index (PSQI) and menopausal symptoms and quality of life were evaluated by the menopause rating scale (MRS) and the Chinese version of World Health Organization quality of life-BREF at the final follow-up in the fourth weekend after beginning.

**RESULTS:** The average scores of PSQI had reduced from  $(13.82 \pm 4.97)$  to  $(8.14 \pm 3.19)$ , 95% CI (– 4.87, – 3.05) after 2-week GGLMT treatment in the fourth week. GGLMT improved symptoms in patients with more severe conditions ( $MRS \geq 16$ ). Three adverse drug reaction, mouth ulcer, constipation, and folliculitis, might be related with GGLMT and disappeared after withdrawals of the treatment.

**CONCLUSION:** For menopausal women suffering from chronic sleep disturbances, our findings suggest that two weeks treatment of GGLMT was safe and effective.

© 2016 JTCM. This is an Open Access article under the CC BY-NC-ND License (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

**Key words:** Menopause; Quality of life; Sleep disturbances; Medicine, Chinese traditional; Guizhi Gancao Longgu Muli Tang

### INTRODUCTION

Sleep disturbances is not only one of the common discomfort of climacteric women, but also one of the unbearable symptoms resulting in poor quality of life (QOL) for menopausal patients.<sup>1,2</sup> The phenomenon appears in over half of menopausal patients and could occur independently or synergistically with many climacteric symptoms which bring them much agony.<sup>3,4</sup> When it comes to promote quality of sleep, benzodiazepine

piners had been considered to be much effective medications on the pharmaceutical market, since it was approved in 1960.<sup>5</sup> Although benzodiazepines, which is older generation of hypnotics, is regarded as prior recommendation in clinical guidelines, it is accepted that this kind of medication might bring many patient adverse effects, such as rebound insomnia, poor judgment, daytime sedation, and so on. As it should be complementary and alternative medications that menopausal patients turn to in order to treat their sleep disturbances and to improve quality of life without adverse drug reaction.<sup>6,7</sup>

Guizhi Gancao Longgu Muli Tang (GGLMT) has been used as sedative therapy by Zhang Zhongjing in his classical Traditional Chinese Medicine (TCM) book, *Shang Han Za Bing Lun* (Explanation and essential prescriptions for a variety of diseases) which was came out since 210 A.D.<sup>8</sup> It is claimed in the interpretations literature that GGLMT can warm invigorate heart yang and suppress hyperactive *Yang* so as to induce a tranquillizing efficacy and improve discomfort of insomnia eventually TCM, a kind of experience medicine according to the TCM theory, indications and contraindications of prescriptions from clinic experience and classical literatures, spreads widely to Japan, South Korea and other areas.<sup>9,10</sup>

Frequently, GGLMT appears in prescriptions for menopausal patients in Chinese mainland.<sup>11</sup> None pharmaceutical companies, unfortunately, plan to perform any clinic controlled study for GGLMT that could be prescribed by any TCM practitioners in China. Our study aimed to evaluate the effect GGLMT on sleep disturbance in menopausal women.

## MATERIALS AND METHODS

### Patient recruitment

It was in TCM Outpatient Clinic of Zhongda Hospital of Southeast University that menopausal women suffering sleep difficulty were recruited in this project. This observation was approved by the Nanjing City Hospital Institutional Review Board. Patients who initially appealed to the TCM Outpatient Clinic because of little efficacy of hormone replacement therapy for sleep difficulty were informed the recruitment on poster in front of hospital gate advertisements from February, 2012 to December, 2014. All menopausal women grasped design and meaning of this study and each informed consent forms were signed willingly without interference. After grasping significant points of the trial, nurses learned training courses to define tasks that were performed according to Good Clinical Practice (GCP) directions. One climacteric woman should pass through two interviews if she was recruited. First of all, she would be asked on some questions about medical history and conducted a relating clinical examination. It was examined in the next interview a medical evaluation

comprised of biochemical function tests, complete blood routine tests and some baseline data, such as quality of life and symptoms. The observation was partly supervised by the Independent Ethics Committee for Clinical Research of Zhongda Hospital affiliated to Southeast University.

### Eligibility criteria

The climacteric patients, whose ages ranged from 41-66 years, were hard to fall into sleep, which more than 45 min were spent on, and had difficulty in sleep duration, which was no more than 6 h. All of them, additionally, concentrated on solving the problem ceaselessly for more than 3 months. Participants in this trial were menopausal women whose total Pittsburg sleep quality index (PSQI) scores were more than 6.

### Ineligibility criteria

A patient would be excluded if she met the following conditions: (a) she was injured in a heavy accident within three months of this trial; (b) working time required in the night; (c) lack of time or timing conflicts, necessary time spent on this trial was insufficient; (d) accompanying diseases including high blood pressure, depression, cardiac arrhythmia, acute myocardial infarction, obstructive sleep apnea hypopnea syndrome, cancer, diabetes, psychosis, restless legs syndrome, and some that might produce interference on result; (e) taking food and medications that might result in changes of histamine, glutamate, gamma-aminobutyric acid (GABA), acetylcholine, serotonin, adenosine, prostaglandins, melatonin or norepinephrine; (f) anomaly quotas which are more than 1.5 times the superior limit for dysfunctions of kidney or liver, (alanine-amino-transferase (ALT): 29 IU/L; serum aspartate-amino-transferase (AST): 25 IU/L; blood urea nitrogen (BUN): 22 mg/dL; serum creatinine: 1.3 mg/dL); (g) Inability to read or write any information and words for this trial.

### Treatment

GGLMT was combination including decoction of four traditional Chinese medications as follows: Guizhi (*Ramulus Cinnamomi* without rinds) 15 g, Zhi Gancao (*Radix Glycyrrhizae Fried*) 30 g, Longgu (raw *Os Draconis*) 30 g and Muli (raw *Concha Ostreae*) 30 g.<sup>9</sup> This decoction combination from pharmacy of Zhongda hospital met international criterions of quality and uniformity and Chinese herbs decoction pieces in the pharmacy were managed by a certified company, Nanjing Pharmaceutical Co., Ltd., (Nanjing, China) which was the good manufacturing procedures (GMP). Except supervising the study, the association had no impact on selecting of the participants, observation design, and any other work.

The Chinese medicine decoction pieces of GGLMT were decocted in a professional microcomputer-controlled boiler purchased from Donghe Technology Company (Xuzhou, China), 400 mL of decoction per

Download English Version:

<https://daneshyari.com/en/article/8818319>

Download Persian Version:

<https://daneshyari.com/article/8818319>

[Daneshyari.com](https://daneshyari.com)