



## Review Article

# Research Progress of Traditional Chinese Medicine Treatment of Insomnia

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### Abstract

With the increasingly growing work and life stress, prevalence of insomnia has been increasing year by year, which has seriously affected people's physical and mental health and quality of life. Benzodiazepines are mainly used to treatment insomnia, but prolonged use of benzodiazepine can lead to dependence and cognitive impairment. Traditional Chinese medicine (TCM) is safe, economical, effective, does not produce drug resistance and addiction, and has unique advantages in the treatment of insomnia. This article summarizes the research progress of TCM treatment of insomnia in recent years.

**Keywords:** Insomnia; Traditional Chinese Medicine; Treatment; Review

Insomnia belongs to the category of "sleeplessness" in ancient books of TCM, which refer to a group of diseases characterized by frequent inability to obtain normal sleep frequently [1]. As one of the most prevalent sleep disorders, insomnia has evolved into a significant societal concern globally, drawing attention from healthcare professionals and various sectors due to its widespread occurrence and the consequential decline in daytime functionality. A 2007 survey by the National Sleep Foundation in the United States revealed that approximately 65% of individuals experience varying degrees of sleep-related issues [2]. A survey conducted by the Chinese Sleep Research Society shows that 38.2% of Chinese adults suffer from insomnia [3]. A 2017 meta-analysis by Cao et al. examined 17 clinical studies with 115,988 cases, indicating an overall insomnia incidence of around 15% in China, slightly lower than in Western countries but comparable to other Asian nations [4]. Persistent insomnia significantly impacts both physical and

mental health, with adults sleeping less than 4 hours per night facing an alarming 180% increase in mortality rates [5]. Research indicates that 50% of insomnia patients exhibit varying degrees of depression and anxiety symptoms, with insomnia potentially serving as an independent risk factor for the development of anxiety or depression [6-8].

Clinically, the treatment of insomnia mainly involves benzodiazepine hypnotic drugs, but prolonged use can result in adverse reactions such as drug dependence and withdrawal symptoms [9]. Traditional Chinese Medicine (TCM), characterized by comprehensive syndrome differentiation and regulation of systemic functional status, presents distinctive advantages in insomnia treatment. TCM exhibits fewer adverse reactions, no dependence, and good compliance, garnering increased attention in clinical practice. This article provides a concise overview of recent research progress in traditional Chinese medicine for treating insomnia, aiming to offer insights for clinicians engaged in the treatment of insomnia.

## **Etiology and pathogenesis**

According to traditional Chinese medicine, the onset of sleep is regulated by the heart spirit, and the normal functioning of the nutrient-defense yin and yang is the basis for ensuring the regulation of insomnia by the heart spirit. Various factors, including external pathogenic influences, unclean diet, emotional imbalances, fatigue, excessive rumination, post-illness recovery, and physical frailty in the elderly, can disrupt the harmony of the heart-mind, preventing the transition from movement to tranquility and resulting in insomnia [1].

The pathogenesis of insomnia is generally characterized by yang exuberance and yin debilitation, leading to an imbalance of yin and yang [10]. TCM, embracing a holistic perspective, attributes insomnia primarily to the heart; however, due to the interconnectedness of the five internal organs, imbalances in liver, spleen, kidney, and lung functions can also contribute. Dysfunction in any specific organ can disrupt the harmony of yin and yang, qi, and blood, manifesting as insomnia. As stated in the "Nanjing" (Classic of Questioning), for a person to sleep normally, the five emotions (spirit, corporeal soul, soul, idea, will) must be in their respective positions [11].

Modern physicians, while differing in their research focuses and perspectives on insomnia's causes and mechanisms, generally concur that its pathological changes involve yang excess and yin deficiency, yin and yang imbalance, and affect various organs such as the heart, liver, gallbladder, spleen, stomach, kidneys, and brain. Pathological factors encompass fire, heat, fatigue, phlegm, dampness, and dietary factors. Gender, age, personality, and constitution differences can result in diverse pathological mechanisms of insomnia, requiring tailored clinical approaches. Deficiency patterns often involve insufficient Qi, blood, essence, and fluid, while excess patterns are typically marked by the obstruction of fire, heat, phlegm, Qi, and blood. Emotional trauma, irregular diet, and overexertion are cited as common causes by Deng Tie-tao, with emotional trauma being the predominant factor. The affected organs include the heart, liver, gallbladder, spleen, and stomach, forming a pathogenesis characterized by yang excess and yin deficiency [12]. Wang Qiu-chu emphasizes psychological triggers for insomnia and proposes liver-focused diagnosis and treatment. Organ dysfunction leading to Qi and blood imbalance is crucial to insomnia development, with emotional factors primarily involving the liver and often affecting the heart, spleen, and kidneys [13]. Gao Rong-lin, drawing on the concept of "unease of the stomach leading to restlessness," identifies the stomach and spleen as the key regulators of Qi movement. Normal Qi movement is deemed essential for sound sleep, and treatment involves tonifying the spleen, promoting Qi transportation, harmonizing the stomach, and facilitating bowel movement, potentially utilizing modified Sijunzi Tang and Banxia Xiexin Tang [14].

## **Clinical research**

Insomnia is treated based on the principles of reinforcing insufficiency and reducing excessiveness and restoring the balance of Yin an Yang [10]. Treatment approaches vary based on whether the syndrome is characterized by excess or deficiency. For excess syndromes, the focus is on reducing the excess, while for deficiency syndromes, efforts are made to supplement the insufficiency. Additionally, treatments aim to calm the spirit and stabilize the will. The differentiation and treatment of insomnia primarily revolve around three theories [15]: (1) Treatment based on the heart: In the "Inner Classic" (Yellow Emperor's Canon of Medicine), insomnia is often discussed in terms of the heart's role as the controller of the spirit. When the heart spirit is restless, it leads to difficulty in sleeping. This is commonly due to blocked emotions, insufficient heart blood, the spirit not keeping to the body, or external evil invasions that disturb the spirit. After major illnesses, when heart blood is deficient, one may experience restlessness and insomnia, which often affect the liver, spleen, and kidneys, and these organs often influence each other, leading to diverse and complex clinical symptoms. (2) Treatment based on phlegm: In the Tang Dynasty, Sun Simiao's "Shengjing Yijin" (Golden Cabinet of Medical Secrets) described a prescription for treating deficiency of the gallbladder with cold symptoms, named "Wen Dan Tang" (Warm Gallbladder Decoction). It addresses restlessness and insomnia following a serious illness caused by gallbladder cold. Modern usage has expanded to include the functions of calming the gallbladder and stomach, resolving phlegm, stopping cough, and treating various symptoms associated with gallbladder deficiency. In the Ming Dynasty, Zhang Jingyue's "Jingyue Quan Shu" (Complete Works of Jingyue) recorded: "For those who cannot sleep due to evil factors, remove the evils and sleep will follow naturally." ... "The phlegm-dampness evil should be resolved with medications like Wen Dan Tang." Modern usage has gradually evolved to include the functions of "Wen Dan Tang for calming the gallbladder and stomach, resolving phlegm and stopping cough, treating gallbladder deficiency with restlessness, insomnia, chest oppression, bitterness in the mouth, vomiting, and acid regurgitation." (3) Treatment based on blood stasis: This originates from Wang Qingren's "Yi Lin Gai Cuo" (Correction of Medical Errors) and the augmented Xue Fu Zhu Yu Decoction, which treats headaches, chest pain, night sweating, mental heat, irritability, frequent dreams, insomnia, restlessness at night, infantile night-time crying, hiccups, dry regurgitation, difficulty drinking water, palpitations, and other chest diseases.

## **Treatment with Modified Traditional Chinese Medicine Formulas**

Notable practitioners have modified and adjusted classic formulas to effectively treat insomnia. For instance, Yang Wanying [16] achieved a 96.4% total effective rate in treating refractory

insomnia using a modified Jia Wei Xue Fu Zhu Yu Decoction. Liu Cailing utilized a modified Suan Zao Ren Decoction for menopausal insomnia in women, with a 94.7% total effective rate [17]. Yin Sheng [18] conducted a study comparing the efficacy of Chai Hu Shu San and Selenium tablets, demonstrating a significantly better outcome with traditional Chinese medicine in terms of cure rates and improvements. Furthermore, Hao Finland and colleagues [19] conducted a randomized study comparing Ban Xia Xie Xin Tang to Estazolam tablets, with Ban Xia Xie Xin Tang showing a significantly higher total effective rate (93.1%) compared to Estazolam tablets (66.7%). In conclusion, traditional Chinese medicine offers a range of effective treatments for insomnia, with modified and adjusted classic formulas showcasing promising results in clinical practice.

### **Treatment with self-formulated formulas**

Chinese Herbal Compounds, known for their holistic and dialectical characteristics, play a pivotal role in regulating the overall functional state of the body. They offer several advantages in treating insomnia, including minimal adverse reactions, no dependence, absence of iatrogenic diseases, and good patient compliance. Qiguangfeng [20] conducted a study with 80 patients diagnosed with chronic insomnia characterized by yin deficiency and phlegm-heat. The treatment group received a formula aimed at nourishing yin, clearing heat, and resolving phlegm, while the control group took estazolam orally for 28 days. Evaluation using the Pittsburgh Sleep Treatment Index revealed a 77.5% effective rate in the treatment group compared to 52.5% in the control group, indicating a statistically significant difference. Teng Jing et al. [21] proposed that human sleep and wakefulness are integral physiological states, and insomnia disrupts the “day vitality-night darkness” physiological balance. They successfully used a morning awakening formula and an evening sleep formula to regulate nutrient movement and meridian activity, achieving positive clinical outcomes. Li Zhimin et al. [22] employed a formula containing tranquilizing and blood-activating herbs to treat 317 cases of insomnia dependent on tranquilizers. The results demonstrated a total effective rate of 86.44%, with observations suggesting some patients experienced clinical withdrawal symptoms after taking tranquilizers for more than 2 months. The average onset time for herbal treatment was 1-2 weeks, and the withdrawal process from Western medicine took 1-3 months or longer.

### **Treatment with Chinese patent medicine**

Chen Xiaomin et al. [23] gathered 60 patients with insomnia accompanied by anxiety, randomly dividing them into a treatment group and a control group. The treatment group received 1 tablet of Deanxit every morning, along with 3 capsules of Wuling capsule after each meal in the morning, afternoon, and evening.

The control group only took 1 tablet of Deanxit every morning. After an 8-week treatment period, the results showed a 93.3% total effective rate in the treatment group, significantly higher than the 63.3% in the control group. He Zhanwang et al. [24] conducted a random division of 120 insomnia patients into treatment and control groups (60 cases each). The control group received Bailemian capsules, while the treatment group was administered Bai Zi Yang Xin pills. The 14-day treatment course revealed an 18.3% cure rate in the treatment group, significantly higher than the 3.3% in the control group. Additionally, the treatment group exhibited better improvements in sleep quality, sleep onset time, and sleep efficiency compared to the control group.

## **Non-drug therapy of traditional Chinese medicine**

### **Acupuncture and moxibustion**

Acupuncture, encompassing various techniques such as scalp acupuncture, body acupuncture, seed needle therapy, acupoint embedding, and moxibustion, is a primary method for treating insomnia in traditional Chinese medicine. Studies have explored its effectiveness: Ying Jianmin treated 60 insomnia patients with acupuncture over a 10-day course, resulting in a 71.67% total effective rate, including 20 cases of clinical recovery [25]. Huang Weiquan utilized acupoint embedding on Fulu (GB 34), Xinsu (BL 23), and Shensu (BL 23) for 84 insomnia patients, achieving a 64.3% cure rate and an 88.1% effective rate after 4 sessions over 5 weeks [26]. Ma Zengbin's meta-analysis of 11 studies on seed needle therapy using RevMan 5.3 software indicated superior efficacy compared to conventional acupuncture and medication groups [27]. Zhang Jun's study on 80 insomnia patients with heart and spleen deficiency showed a 95.0% effective rate with transcervical moxibustion at Shenque acupoint, outperforming oral Chinese medicine treatment [28].

### **Ear acupressure, cupping, tuina (massage), TCM foot bath**

Deng Xiaoying's study on 56 insomnia patients incorporated traditional Chinese medicine foot bath, foot reflexology massage, and fire cupping, achieving a total effective rate of 96.4%, surpassing the control group using Eszopiclone alone [29]. Cao Miao's meta-analysis of 11 tuina (massage) studies for primary insomnia using RevMan 5.3 software found tuina treatment to be more effective than oral sleep medications and other traditional Chinese medical therapies, especially when combined with head and back tuina [30]. Li Xiaoting's study on 100 patients with sleep disorders after hormone treatment introduced ear acupressure and herbal paste application, resulting in significantly lower scores on the Pittsburgh Sleep Quality Index (PSQI), Hamilton Anxiety Scale (HAMA), and Hamilton Depression Scale (HAMD) compared to the control group [31]. Chen Yongru's randomized study on 150 insomnia patients found that the combination of ear acupressure

and Deng Tie Tao's traditional Chinese medicine foot bath formula significantly outperformed routine nursing interventions, with a total effectiveness rate of 94.67% compared to 77.33% in the control group [32]. The results suggest that this combination is highly effective in treating insomnia and warrants further promotion.

## Conclusion

In recent years, TCM has demonstrated notable progress in addressing insomnia, offering advantages such as simplicity, effectiveness, and cost-effectiveness. The range of treatment methods has expanded to include oral administration, acupuncture, point application, and foot baths. Despite these advancements, there are still several shortcomings in TCM's approach to insomnia. First, rigorous research designs with small sample sizes remain a challenge. Existing literature often emphasizes efficacy observation and clinical experience summaries, lacking standardized randomized controlled duplicate double-blind studies. Second, the absence of a unified standard for dialectical typing contributes to a lack of consensus on diagnostic standards and efficacy evaluation systems. Third, insufficient research exists on the mechanisms underlying TCM's treatment for insomnia, with a paucity of animal experiments to provide deeper insights. Patients dependent on tranquilizers often suffer from poor sleep quality, nighttime restlessness, daytime drowsiness, and memory impairment. Clinical use of anxiolytic medications may not always be ideal. The theory of "daytime drowsiness leading to nighttime restlessness" is not universally understood, and there is a singular focus on sedative and tranquilizing effects during the night, neglecting the importance of improving daytime social function in insomnia treatment. To address these challenges, future work should further standardize research designs and clinical study models. Seek widely recognized effective treatments and formulas based on the traditional TCM theories, combine modern medical understanding of the etiology and pathogenesis of insomnia, and innovate thinking to unify dialectical typing. Develop animal models that conform to the pathological characteristics of the "syndrome" for basic experimental research in TCM to guide clinical practice and further promote the modernization and internationalization of TCM.

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