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Clinical Observation of Bagua Auricular Therapy for Insomnia Due to Heart-Kidney Disharmony

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Abstract

Objective: To evaluate the clinical efficacy of Bagua auricular therapy in treating insomnia of the heart-kidney disharmony type. **Methods:** A total of 81 patients with insomnia of the heart-kidney disharmony type admitted to Shenzhen Hospital of Guangzhou University of Chinese Medicine from January to October 2024 were randomly allocated into an observation group (n = 40) and a control group (n = 41). Both groups received basic treatment, while the observation group received additional Bagua auricular therapy for 2 weeks. Next, clinical efficacy, traditional Chinese medicine (TCM) syndrome scores, Pittsburgh Sleep Quality Index (PSQI) and Self-Rating Anxiety Scale (SAS) were compared between the two groups. **Results:** The observation group showed a significantly higher total effective rate and greater improvements in TCM syndrome scores, SAS, and PSQI compared to the control group ($P < 0.001$). **Conclusion:** Bagua auricular therapy can effectively improve insomnia of the heart-kidney disharmony type, alleviate the symptoms of heart-kidney disharmony as well as anxiety and depression, and enhance the sleep quality of patients.

1 Introduction

Insomnia is a subjective experience characterized by insufficient sleep time and decreased sleep quality, which has become an important issue affecting public health. Epidemiological surveys showed that 60.4% of the population in China have symptoms of sleep disorders, among which about 10% of adults suffer from insomnia symptoms [1]. Numerous studies have confirmed that insomnia is closely related to various physical and mental illnesses, including cardiovascular disease [2], cerebrovascular diseases [3,4], depression [5], and anxiety disorders [6]. Furthermore, insomnia has been identified as a significant risk factor for suicidal thoughts and behaviors [7], underscoring the critical public health implications of effective insomnia intervention. Research has found that effective interventions for insomnia may become an important strategy for preventing mental illness [8]. At present, cognitive-behavioral therapy (CBT-I) and drug therapy are mainly used in clinical practice, but CBT-I has limitations such as high implementation costs and a lack of professional personnel [9]. Long-term use of sedative hypnotic drugs may result in adverse consequences such as drug dependence, excessive sedative effects, addiction, and cognitive dysfunction. [10]. The external treatment methods of traditional Chinese medicine (TCM) have advantages such as high safety, good compliance, and affordability [11]. Especially, ear acupuncture therapy has shown unique therapeutic effects in improving primary insomnia [12]. Based on the TCM theory of "heart-kidney interaction", this study innovatively integrated the Yin-Yang balance theory of the I Ching with traditional auricular point therapy, and conducted a randomized controlled clinical trial in patients with insomnia of the heart-kidney disharmony type. Through systematic observation of the clinical efficacy of the auricular point seed-pressing intervention, this study aimed to establish a non-pharmacological therapy featuring TCM characteristics, stable therapeutic effects, and good clinical applicability.

2 Subjects and methods

2.1 General information

This study utilized a randomized controlled trial design, and included 81 patients who met the diagnostic criteria for insomnia of the heart-kidney disharmony type and admitted to the Oncology Department and TCM Comprehensive Treatment Area of Shenzhen Hospital of Guangzhou University of TCM from January 2024 to October 2024. Patients in the Oncology Department were enrolled based on the following rationale: (1) cancer-related insomnia is highly prevalent, and the heart-kidney disharmony pattern is commonly observed in this population due to chronic illness and psychological stress; (2) the TCM Comprehensive Treatment Area at our hospital provides integrated TCM services for oncology patients, where insomnia is frequently identified as a coexisting condition requiring intervention; (3) all enrolled patients met the independent diagnostic criteria for insomnia of the heart-kidney disharmony type, regardless of their primary disease status. The study protocol was approved by the Ethics Committee of Shenzhen Hospital of Guangzhou University of TCM (Approval No.: GZYLL(KY)-2025-113). Written informed consent was obtained from all participants. The subjects were divided into an observation group (n = 40) and a control group (n = 41) using a random number table method. The baseline data of the two groups were balanced and comparable.

Sample size estimation. This study used the Pittsburgh Sleep Quality Index (PSQI) as the primary efficacy indicator. The significance level was set at $\alpha = 0.05$ (two-sided), and the power $(1-\beta)$ was set at 0.90. The sample size for comparing two independent sample means was calculated using the formula: $n = 2 \times (Z\alpha/2 + Z\beta)^2 \times S^2/\delta^2$. Based on published literature [13], the post-treatment PSQI score was 10.17 ±

1.92 in the control group and 7.92 ± 1.36 in the treatment group. The between-group difference was δ = 10.17 − 7.92 = 2.25 points, and the pooled standard deviation was S=1.66 points,Zα/2=1.96,Zβ =1.282, the calculated required sample size was approximately 23 subjects per group. Considering a 20% dropout rate, the minimum required sample size was 29 per group (total n = 58). Ultimately, this study enrolled 81 patients, who were randomly allocated to the observation group (n = 40) and the control group (n = 41).

General demographic characteristics and clinical baseline data of subjects in the control and observation groups were recorded and summarized in Table 1.

Table 1 Baseline Characteristics of the Study Participants.

Variable	/	Control Group n (%)/(M ± SD)	Observation Group n (%)/(M ± SD)	χ^2/t	*P*
Sex	Male	19 (46.34%)	17 (42.5%)	0.121	0.728
	Female	22 (53.66%)	23 (57.5%)		
Age (years)	/	55.00 ± 7.28	53.12 ± 7.09	1.174	0.244
	Unknown	6 (14.63%)	6 (15%)		
Marital Status	Married	35 (85.37%)	33 (82.5%)	1.047	0.593
	Unmarried	0 (0%)	1 (2.5%)		
Ethnicity	Han	41 (100%)	40 (100%)	/	/
	Worker	38 (92.68%)	35 (87.5%)		
Occupation	Farmer	1 (2.44%)	0 (0%)	2.397	0.302
	Teacher	2 (4.88%)	5 (12.5%)		
Disease Duration (weeks)	/	29.61 ± 9.63	29.95 ± 9.41	-0.161	0.873
Comorbidity-Coronary Heart Disease	No	28 (68.29%)	27 (67.50%)	0.006	0.939
	Yes	13 (31.71%)	13 (32.50%)		
Comorbidity-Diabetes	No	33 (80.49%)	32 (80.00%)	0.003	0.956
	Yes	8 (19.51%)	8 (20.00%)		
Comorbidity-Hypertension	No	30 (73.17%)	29 (72.50%)	0.005	0.946
	Yes	11 (26.83%)	11 (27.50%)		
Medical History	Oncology	33 (80.49%)	34 (85%)	0.288	0.591
	Other diseases	8 (19.51%)	6 (15%)		
Severity	Mild	1 (2.44%)	4 (10.00%)	3.253	0.197
	Moderate	24 (58.54%)	26 (65.00%)		
	Severe	16 (39.02%)	10 (25.00%)		
Personal History	None	34 (82.93%)	36 (90%)	0.863	0.353
	Smoking	7 (17.07%)	4 (10%)		
Surgical History	No	41 (100%)	37 (92.5%)	3.193	0.074
	Yes	0 (0%)	3 (7.5%)		

2.2 Diagnostic criteria

2.2.1 Diagnostic criteria of western medicine

This study established diagnostic criteria based on the Chinese Guidelines for the Diagnosis and Treatment of Insomnia [7]. Patients were required to present with at least one of the following clinical symptoms: difficulty falling asleep (sleep onset > 30 minutes), difficulty maintaining sleep (nocturnal awakenings ≥2 times), early morning awakening (waking ≥ 1 hour earlier than desired with inability to resume sleep), subjective decline in sleep quality, or post-sleep discomfort, which should persist during sufficient sleep time (≥ 6.5 hours/night) and in a suitable sleep environment. At the same time, at least one manifestation of daytime functional impairment must be present, including but not limited to cognitive dysfunction (e.g. inattention, memory decline, or reduced work efficiency), emotional abnormalities (e.g. irritability, anxiety, and depression), physical symptoms (e.g. daytime sleepiness and headaches), impaired social function (e.g. increased risk of operational errors or reduced social competence), or excessive attention to sleep problems. All symptoms must be ruled out as being caused by other medical conditions or mental disorders.

2.2.2 Diagnostic criteria of TCM

This study established the diagnostic criteria for insomnia of the heart-kidney disharmony type based on the Clinical Practice Guidelines for Insomnia in Traditional Chinese Medicine (WHO/WPO) [8]. The core manifestations were sleep disorders (prolonged sleep latency), early awakening, or difficulty maintaining sleep; in severe cases, the patient may experience sleeplessness throughout the night. Accompanying symptoms should include at least two symptoms such as restlessness and dizziness, and tinnitus, or manifestations of kidney Yin deficiency such as feverish sensations in the palms, soles, and chest, night sweats, or sexual hypofunction. Female patients may also experience menstrual disorders. In terms of physical signs, it is necessary to have characteristic tongue and pulse manifestations such as red tongue tip, peeling tongue coating, and fine pulse count. The diagnosis should meet at least one major sleep disorder, accompanied by two or more symptoms, and combined with characteristic tongue and pulse signs.

2.3 Inclusion criteria

1) Meet the above diagnostic criteria; 2) Age between 18 and 70 years old; 3) Pittsburgh Sleep Quality Index (PSQI) score ⩾ 7 points. 4) Voluntarily participate in this study and sign an informed consent form.

2.4 Exclusion criteria

1) Pregnant or lactating women; 2) Patients with cognitive dysfunction or language communication disorders; 3) Combined ear skin lesions (including eczema, ulcers, frostbite, etc.); 4) Insomnia patients secondary to organic diseases (advanced malignant tumors, uncontrolled cardiovascular and cerebrovascular diseases, endocrine and metabolic disorders, etc.) or acute conditions (infectious fever, postoperative status, chronic pain, etc.); 5) Current participation in other interventional clinical studies.

2.5 Termination and exclusion criteria

1) Serious adverse events or special physiological changes that render study continuation impossible; 2) Voluntarily withdraw or lost to follow-up; 3) Insufficient treatment compliance (failure to complete the prescribed course) or concurrent use of other interventions that may compromise the assessment of study outcomes.

2.6 Treatment methods

2.6.1 Control group

Patients in the control group received basic treatment [14], which included the following components: (1)

Health education: individualized sleep hygiene counseling covering regular sleep-wake schedule, avoidance of caffeine/alcohol before bedtime, optimal sleep environment, limited daytime napping, and restricted electronic device use before sleep; (2) Exercise guidance: moderate aerobic exercise for 30–45 minutes/day, ⩾5 days/week, completed ⩾3 hours before bedtime, with intensity individually adjusted for physically limited patients; (3) Lifestyle guidance: TCM-based dietary recommendations (Yin-nourishing, spirit-calming foods), stress management techniques (diaphragmatic breathing, progressive muscle relaxation), and restriction of non-sleep in-bed activities. The basic treatment was initiated at enrollment and continued for 14 days, with adherence assessed and reinforced at follow-up visits (twice weekly).

2.6.2 Observation group

This study employed a standardized auricular point intervention protocol. Subjects were placed in a sitting or lateral recumbent position, and the treatment area of the ear was disinfected with 75% alcohol cotton balls using an outward spiral motion (extending 2 cm beyond the target zone). Based on the Eight Trigrams (Bagua) theory of the I Ching, positive reaction points within the trigram zones were precisely identified through a combination of visual inspection and palpation, including pathological features such as pigmentary changes (erythema, leukoderma, hyperpigmentation), morphological alterations (depressions, nodules), and epidermal abnormalities (scaling, fissuring). The specific identification criteria for positive reaction points were as follows: Positive reaction points were identified through a two-step process combining visual inspection and palpation, based on established auricular diagnostic criteria in TCM literature [15]. Visual inspection criteria: Color changes were interpreted according to standard TCM auricular diagnostics: red indicating heat/inflammation, dark brown indicating blood stasis, and pale indicating deficiency or chronic conditions. Palpation criteria: Using a sterile auricular probe, the practitioner applied gentle pressure to detect tenderness, nodularity, or altered tissue consistency within each trigram zone. Points exhibiting marked tenderness or palpable morphological changes were designated as positive reaction points. To ensure reproducibility of the localization method, consistency comparisons of localization results were performed on the same patient by the same operator at different time points. The practitioner documented the identified positive reaction points in each trigram zone at every session, and the stability of localization results was monitored throughout the 14-day treatment course. The application sequence strictly followed the principle of Yin-Yang harmonization: for the "Water and Fire in Harmony" of Kan trigram, the treatment was performed in the order of Li; for the "Mountain and Lake Ventilating" of Gen trigram, the treatment was performed in the order of Dui. The stimulation frequency was set according to the characteristics of each trigram: Kan trigram (every 6 stimulations as a cycle), Li trigram (every 3 stimulations as a cycle), Gen trigram (every 7 stimulations as a cycle), and Dui trigram (every 2 stimulations as a cycle). The intervention was administered 4 times per day at fixed time points (08:00, 12:00, 16:00, and 20:00), with each session lasting until a warm sensation was felt in the auricle (approximately 2 minutes). The entire treatment course lasted 14 days, with interventions performed twice per week on a fixed schedule (Monday and Thursday), for a total of 4 treatment sessions. Clinical efficacy and safety indicators were regularly assessed throughout the treatment period.

For auricular Bagua localization, the helix root should be identified. A horizontal axis was drawn along the line connecting its inner and outer aspects (the inner aspect starts from the supratragic notch, and the

outer aspect ends at the medial edge of the antihelix). Then, from the midpoint of this horizontal axis, a vertical axis at a 90-degree angle was drawn to determine the four cardinal directions (East-Zhen, South-Li, West-Dui, North-Kan). The area of the ear apex corresponded to the foot and represented the North-Kan trigram. The area of the earlobe corresponded to the head and represented the South-Li trigram. The outer edge of the line connecting the helix root corresponded to the East-Zhen trigram, and the inner edge corresponded to the West-Dui trigram. The four corner directions were then filled in sequentially according to the order of the Later Heaven Bagua diagram (Figure 1).

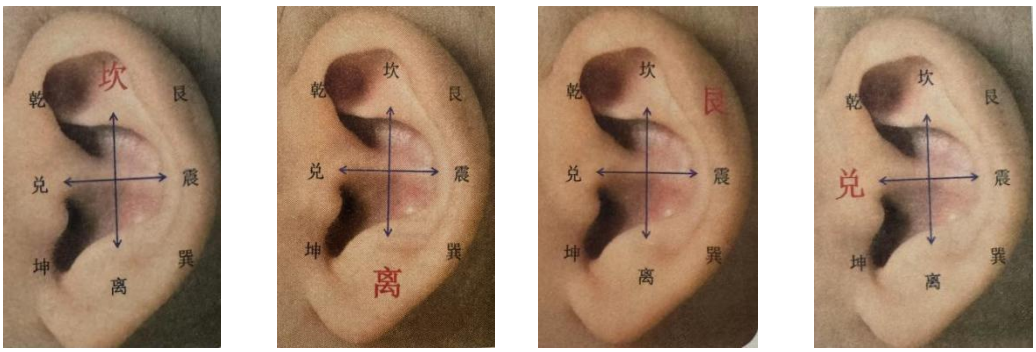

Figure 1 Trigram Diagram of "Water and Fire in Harmony" and "Mountain and Lake Ventilating".

2.7 Observation indicators

This study adopted a multi-dimensional evaluation system to conduct a comprehensive assessment of the intervention effects. The PSQI [16], a scale with good reliability and validity, was selected as the primary efficacy indicator. The PSQI comprises 19 self-rated items grouped into 7 component scores: subjective sleep quality (1 item, scored 0-3), sleep latency (2 items, scored 0-3), sleep duration (1 item, scored 0-3), habitual sleep efficiency (1 item, scored 0-3), sleep disturbances (9 items, scored 0-3), use of sleeping medication (1 item, scored 0-3), and daytime dysfunction (2 items, scored 0-3). Each component is scored on a 0-3 scale, with higher scores indicating poorer sleep quality. The global PSQI score is the sum of the seven component scores, ranging from 0 to 21 points. A global score > 5 indicates poor sleep quality, and a cutoff of $\geqslant$ 7 points was applied as the inclusion criterion in this study. The primary endpoint was the change in global PSQI score from baseline to each assessment time point (Days 3, 7, 10, and 14). The score is negatively correlated with sleep quality (lower scores reflect better sleep). The TCM syndrome score scale was used as the secondary efficacy indicator, which included 4 primary symptoms (difficulty falling asleep, sleep interruption, insomnia throughout the night, and frequent dreams) and 6 secondary symptoms (palpitations, dizziness, tinnitus, soreness and weakness of waist and knees, tidal fever and night sweats, dry mouth). Symptoms were rated on a scale of 0 to 6 according to their severity, with a total score of 48. A higher score indicated more prominent clinical symptoms. Meanwhile, the Self-Rating Anxiety Scale (SAS) was applied to evaluate changes in psychological status. This scale had a total score of 80, with a standardized score of $\geqslant$ 50 as the cutoff for abnormal anxiety (50-59 as mild anxiety, 60-69 as moderate anxiety, and $\geqslant$ 70 as severe anxiety).

Clinical efficacy evaluation. Clinical efficacy was classified into four categories: cure, significantly effective, effective, and ineffective, based on the efficacy index calculated from the TCM syndrome scale total score, according to the standardized criteria established in the Guiding Principles for Clinical Research of New Chinese Medicines [17]. The efficacy index was defined as [(Total score before treatment-Total score after treatment)/Total score before treatment] $\times$ 100%. The classification criteria

were: cure, efficacy index ⩾ 95%; significantly effective, efficacy index ⩾ 70% and < 95%; effective, efficacy index ⩾ 30% and < 70%; and ineffective, efficacy index < 30%. The total effective rate was calculated as the proportion of patients classified as cure, significantly effective, or effective. Efficacy classification was performed at the end of the 14-day treatment course.

2.8 Statistical methods

Statistical analyses were performed using SPSS 26.0 software. For continuous data, after normality assessment using the Shapiro-Wilk test and homogeneity of variance assessment using Levene's test, intergroup comparisons were conducted using independent samples t-test for data that followed a normal distribution with equal variances, while non-normally distributed data were analyzed using the Mann-Whitney U test. Intragroup comparisons before and after treatment were performed using paired t-test. Categorical data were expressed as frequencies (percentages), and intergroup comparisons were conducted using the chi-square test or Fisher's exact test. All statistical tests were two-sided, and a P-value < 0.05 was considered statistically significant.

3 Results

3.1 PSQI score comparison between two groups before and after treatment

There was no significant difference in PSQI scores between the two groups before treatment (P > 0.05), indicating comparability. The PSQI scores of Observation groups were decreased at 3, 7, 10, and 14 days after treatment (P < 0.05), and the scores of the observation group were significantly lower than those of the control group (P < 0.05). Moreover, there was a significant difference in PSQI scores between the two groups with prolonged treatment time (Table 2).

Table 2 Comparison of PSQI scores between two groups of patients before and after treatment.

Group	n	Time	PSQI
Control group	41	Before treatment	18.20±3.09
		After 3 days of treatment	17.34±3.23
		After 7 days of treatment	17.10±3.40
		After 10 days of treatment	17.07±3.23
		After 14 days of treatment	17.00±3.04△
Observation group	40	Before treatment	18.35±2.14
		After 3 days of treatment	15.3±8.495△▲
		After 7 days of treatment	14.88±5.20△▲
		After 10 days of treatment	12.68±8.66△▲
		After 14 days of treatment	12.38±8.63△▲

Control group: △Compared with before treatment, $P < 0.05$; Observation group: ▲Compared with the control group, $P < 0.05$.

3.2 Comparison of TCM syndrome scale scores before and after treatment between the two groups

Before treatment, the scores of the TCM Syndrome Scale displayed no statistically significant difference between the two groups of patients (P > 0.05), indicating comparability of the baseline between the two groups. After 3, 7, 10, and 14 days of treatment, the efficacy scores of the main symptoms and TCM syndromes in both groups were decreased (P < 0.05), which were lower in the observation group than the control group (P < 0.05), as shown in Table 3. The

observation group showed a sharp reduction in main symptom scores as early as day 3, followed by a gradual decline through day 10; notably, the main symptom score at day 14 was slightly higher than that at day 10, suggesting a plateau effect in the later stage of treatment. Similarly, the secondary symptom scores in the observation group decreased markedly by day 3 ($P < 0.05$) and continued to decline gradually until day 10, with a minor rebound at day 14. In the control group, the secondary symptom scores showed only a minimal reduction at day 3 and remained virtually unchanged thereafter.

Table 3 Comparison of TCM syndrome scale scores before and after treatment between the two groups.

Group	n	Time	Main Symptoms	Secondary Symptoms	TCM Syndrome Scale
Control group	41	Before treatment	11.32±4.186	5.39±2.626	16.71±5.53
		After 3 days of treatment	10.98±4.174△	5.07±2.494△	16.05±5.65△
		After 7 days of treatment	10.88±3.743△	5.07±2.392△	15.95±5.15△
		After 10 days of treatment	10.78±3.712△	5.07±2.453△	15.85±5.16△
		After 14 days of treatment	10.63±3.673△	4.88±2.315△	15.51±4.91△
Observation group	40	Before treatment	11.85±5.404	5.63±2.959	17.48±7.04
		After 3 days of treatment	5.55±2.81△▲	4.8±2.431△	10.35±4.57△▲
		After 7 days of treatment	4.97±2.896△▲	4.68±2.379△	9.65±4.66△▲
		After 10 days of treatment	4.33±3.075△▲	4.58±2.252△	8.90±4.74△▲
		After 14 days of treatment	4.4±3.02▲△	4.63±2.393△	9.03±4.79△▲

Control group: △Compared with before treatment, $P < 0.05$; Observation group: ▲Compared with the control group, $P < 0.05$.

3.3 Comparison of SAS scores between two groups before and after treatment

There was no statistically significant difference ($P > 0.05$) in the SAS score between the two groups of patients before treatment. The observation group showed a progressive decrease in SAS scores at each assessment time point, whereas the control group remained largely unchanged throughout the treatment course. The scores of the observation group were lower than those of the control group ($P < 0.05$), as shown in Table 4.

3.4 Comparison of clinical efficacy between two groups

3.4.1 Specificity

The total effective rate comparison between the two groups of patients after intervention was exhibited in Table 5. The total effective rate of the control group and observation group was 21.95% and 87.5%, respectively, indicating that the total effective rate was higher in the treatment group than the control group ($P < 0.001$). Moreover, no patient in the control group

achieved cure or significantly effective outcome, whereas the observation group had a considerable proportion of cure and significantly effective cases. This disparity in the distribution of efficacy grades highlights the substantial advantage of Bagua auricular therapy over basic treatment alone.

Table 4 Comparison of SAS scores between two groups before and after treatment.

Group	n	Time	SAS
Control group	41	Before treatment	41.78±5.23
		After 3 days of treatment	41.61±5.40
		After 7 days of treatment	41.61±5.31
		After 10 days of treatment	41.32±5.31△
		After 14 days of treatment	41.12±4.99△
Observation group	40	Before treatment	39.95±5.89
		After 3 days of treatment	37.55±5.04▲△
		After 7 days of treatment	36.52±4.86▲△
		After 10 days of treatment	36.05±4.71▲△
		After 14 days of treatment	35.65±4.58▲△

Control group: △Compared with before treatment, $P < 0.05$; Observation group: ▲Compared with the control group, $P < 0.05$.

Table 5 Comparison of clinical efficacy between two groups (Unit: number (%)).

Group	n	Cure	Significantly effective	Effective	Ineffective	Total effective rate	χ^2	p
Control group	41	0	0	9	32	9(21.95%)	43.126	<0.001
Observation group	40	3	20	12	5	35(87.5%)		

4 Discussion

4.1 Optimization of extraction condition

Insomnia has become a global public health problem, with an increasing incidence rate according to epidemiological studies [18]. In recent years, there has been a clear trend of younger onset of insomnia. Chronic insomnia not only seriously affects the quality of life of patients, but also easily triggers emotional disorders such as anxiety, causing significant burdens on individual physical and mental health as well as socio-economic development [19]. At present, the main treatment method in modern medicine is drug therapy. Although Western drug treatment for insomnia achieves rapid effects, long-term pharmacotherapy may cause damage to the heart, brain and kidneys, affecting brain thinking, memory functions, social functions, etc. [16]. Modern research has found that auricular seed embedding, which stimulates commonly used acupoints such as the Shenmen and Sympathetic points on the auricle of insomnia patients, can bidirectionally regulate nervous system and inhibit cerebral cortical excitability, thereby alleviating insomnia symptoms [20]. In addition, research has revealed that the pressure stimulation of ear acupressure pills can excite the vagus nerve, effectively counteract excessive excitation of the sympathetic nervous system, alleviate anxiety and depression, regulate the concentration of neurotransmitters such as 5-HT and

NE in the central nervous system, increase melatonin secretion levels, and thus improve sleep rhythm and depth [21].

In the theoretical system of TCM, insomnia falls under the category of "sleeplessness", with fundamental pathogenesis involving disharmony between Yin and Yang, and failure of defensive Yang to enter the Yin phase. Clinically, it often presents with predominantly deficiency patterns, while cases with a prolonged course frequently exhibit complex pathogenesis with intermingled deficiency and excess [22,23]. Studies have indicated that the heart-kidney disharmony pattern constitutes approximately 20.75% of all insomnia cases [24]. The core pathogenesis of this pattern lies in the depletion of kidney Yin, which fails to nourish the heart fire upward, coupled with the weakness of heart Yang, which is unable to warm the kidney water downward. Ultimately, this leads to the disharmony of the mutual restriction and promotion between heart fire and kidney water [25]. The Medical Mind Realizations (Yixue Xinwu) explicitly pointed out that deficiency of kidney essence causes malnourishment of the spirit. Deficient kidney water fails to nourish heart fire downward, resulting in the pathological state of heart-kidney disharmony, characterized by listlessness during the day and inability to sleep at night [26]. The treatment should be based on the principle of "nourishing Yin, reducing fire, and harmonizing the heart and kidney", so as to restore the water-fire harmony, calm the spirit, and induce tranquil sleep.

From a modern neuroscience perspective, auricular therapy modulates sleep through the auricular branch of the vagus nerve (ABVN), which projects to the nucleus tractus solitarius and subsequently regulates sleep-wake related brain regions [27]. Transcutaneous auricular vagus nerve stimulation has been shown to improve sleep quality by enhancing parasympathetic tone and correcting sympathetic-vagal disharmony [28]. Functionally, the "Water and Fire in Harmony" (Kan-Li) configuration in Bagua theory corresponds to the restoration of autonomic balance through vagal modulation, while the traditional concept of "heart-kidney interaction" aligns with contemporary understanding of neuro-visceral integration. This integration of TCM theory with neurophysiological mechanisms provides a coherent framework for understanding the clinical effects observed in this study.

Yi-medicine theory, rooted in Taiji thinking and integrated with Xiang-Shu (image-number) reasoning, employs the Yin-Yang and Bagua (Eight Trigrams) principles from the I Ching to construct a system for disease diagnosis and treatment. The I Ching stated that the greatest model is heaven and earth, and the greatest transformation is the four seasons. Meanwhile, the Huangdi Neijing said that humans correspond to heaven and earth, and resonate with the sun and moon. Together, these theories lay the theoretical foundation of TCM's "correspondence between heaven and humans". As Simiao Sun stated, "without understanding the I Ching, one cannot be called a great physician", profoundly revealing the homology and complementarity between Yi studies and medicine. On one hand, its holistic view holds that humans and the natural environment form an inseparable organic whole. On the other hand, its concept of balance emphasizes the dynamic and coordinated relationship between the internal body and the external environment. This concept is inherently consistent with the bio-psycho-social medical model advocated by modern medicine, evolving into a "holistic medicine" system that integrates traditional wisdom with contemporary medical concepts.

Based on the Yi-medicine theory, this study innovatively integrated Bagua (Eight Trigrams) theory with auricular therapy, selecting the Kan, Li, Gen, and

Dui trigrams for intervention. Specifically, the Kan trigram (associated with Water) corresponded to kidney function, exerting the effect of nourishing Yin and subduing Yang; the Li trigram (associated with Fire) related to the heart-spirit, which can regulate the sleep-wake cycle. The combination of Kan and Li trigrams creates the configuration of "Water and Fire in Harmony", promoting the intersection of heart and kidney and the harmony of Yin and Yang. The Gen trigram (associated with Earth) governs the transformation and transportation functions of the spleen and stomach, while the Dui trigram (associated with Metal) regulates the smooth flow of Qi and blood. Their synergistic interaction constitutes the pattern of "Mountain and Lake Ventilating", serving to unblock the meridians and harmonize Qi-blood. The results of this study demonstrated that the treatment group had significantly better improvements in PSQI score, SAS score, and TCM syndrome score than the control group at each time point after intervention (days 3, 7, 10, and 14) ($P < 0.05$). Furthermore, the observation group achieved a markedly higher total effective rate compared to the control group, with a notable proportion of cure and significantly effective outcomes. This result confirmed that the therapy can effectively promote the upward replenishment of kidney-Yin and the downward submergence of heart-Yang, and rebuild the physiological state of Yin-Yang balance between heart and kidney, which is highly consistent with the theory of "fire returning to the Kan position, and water reaching the Li palace" in the Zhong Zang Jing [29]. In addition, Bagua auricular therapy had clinical advantages of simple operation facilitating widespread application, high safety with minimal adverse effects, cost-effectiveness, and high patient acceptability, providing an innovative intervention for the clinical treatment of insomnia of the heart-kidney disharmony type.

This study has several limitations that should be acknowledged. First, the intervention period was relatively short (14 days), and no follow-up assessment was conducted after the completion of treatment. Insomnia is recognized as a chronic condition with high relapse rates, and short-term improvements observed during the intervention period do not guarantee sustained efficacy over time. Without longitudinal follow-up data, we cannot determine whether the beneficial effects of Bagua auricular therapy persist after discontinuation of treatment, nor can we evaluate the long-term stability of the restored heart-kidney balance. Future studies should incorporate extended follow-up periods to assess the durability of treatment effects and identify potential predictors of relapse. Second, this was a single-center study with a small sample size, which may limit the generalizability of the findings to broader populations. Third, the outcome measures relied primarily on subjective scales, and objective sleep monitoring tools such as polysomnography or actigraphy were not employed. Fourth, the enrolled population was recruited from the Oncology Department and TCM Comprehensive Treatment Area, which may carry a risk of selection bias due to the higher baseline prevalence of anxiety and depression among oncology patients. This limits the generalizability of our findings to the general insomnia population, and caution should be exercised when extrapolating the results to non-oncology settings. These limitations should be considered when interpreting the clinical implications of our results.

5 Conclusion

This study corroborated that Bagua auricular therapy, as an innovative development of TCM characteristic therapies, has significant efficacy in treating insomnia of the heart-kidney disharmony type, while having advantages such as simple operation, good safety, high patient acceptability, and cost-effectiveness, providing a new option for non-pharmacological treatment of insomnia. However, this study has

limitations such as a small sample size, a single-center design, and a short follow-up period. Future research is recommended to conduct multi-center large-sample randomized controlled trials, extend the intervention period and long-term follow-up, and establish a multidimensional evaluation system that contains physiological indicators, psychological scales, and social function assessments.

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Not applicable.

Conflicts of Interest

The authors declare that there is no conflict of interests.

Author Contributions

X.W. and Y.F. conceived the study and secured funding; X.W., D.L. and Y.W. conducted experiments; Q.X. and Y.H. analyzed data; S.L. and Y.F. supplied experimental resources and critical advice. All authors drafted and revised the manuscript and approved the final version.

Ethics Approval and Consent to Participate

The study protocol was approved by the Ethics Committee of Shenzhen Hospital of Guangzhou University of TCM (Approval No.: GZYLL(KY)-2025-113). Written informed consent was obtained from all participants.

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Availability of Data and Materials

The data presented in this study are available on request from the corresponding author.

Supplementary Material

Not applicable.

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