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Clinical Study

Clinical observation of kidney-tonifying and mind-calming acupuncture therapy in the treatment of perimenopausal insomnia

“补肾安神”针刺疗法治疗围绝经期失眠的临床观察

YANG Wenjia (杨文佳)[1], YU Xintong (于心同)[1], ZHAO Na (赵娜)[1], XIE Chen (谢晨)[2], LI Jinjin (李金金)[1], GAO Xiaolin (高晓林)[3], FU Cong (付聪)[1,4,5], CHEN Yunfei (陈云飞)[1]

1 Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of Traditional Chinese Medicine, Shanghai 200437, China

2 Shanghai Research Institute of Acupuncture and Meridian, Shanghai University of Traditional Chinese Medicine, Shanghai 200030, China

3 Shanghai Fourth People’s Hospital Affiliated Tongji University, Shanghai 200434, China

4 Huashan Hospital, Fudan University, Shanghai 200040, China

5 Sleep and Wake Disorders’ Center of Fudan University, Shanghai 200040, China

Abstract

Objective: To observe the effects of kidney-tonifying and mind-calming acupuncture therapy on sleep, mood, sex hormone levels, and traditional Chinese medicine (TCM) symptoms in patients with perimenopausal insomnia (PMI).

Methods: A total of 90 patients with PMI were randomly divided into a treatment group and a control group, with 45 cases in each group. Patients in the treatment group were treated with acupuncture at Shenshu (BL23), Taixi (KI3), Baihui (GV20), and Anmian (Extra). The control group was treated with sham acupuncture. Both groups were treated 3 times a week for 4 weeks. Pittsburgh sleep quality index (PSQI) and insomnia severity index (ISI) were used to evaluate the sleep quality of the subjects before treatment, after treatment, and 1 month after treatment (follow-up). Beck depression inventory (BDI) and Beck anxiety inventory (BAI) were used to evaluate the depression and anxiety of the subjects before treatment, after treatment, and at 1-month follow-up. The TCM symptom scale was used to evaluate the TCM symptoms of the subjects before treatment, after treatment, and 1 month after treatment. Serum levels of estradiol (E_2), follicle-stimulating hormone (FSH), and luteinizing hormone (LH) were measured before and after treatment.

Results: During the study, 2 cases dropped out of the treatment group, and no cases dropped out of the control group. The PSQI scores of the treatment group were significantly lower after treatment and at 1-month follow-up compared with those before treatment (P<0.05), and the difference was statistically significant compared with that of the control group (P<0.05). In the control group, the PSQI score was significantly lower after treatment compared with before treatment (P<0.05), and the difference was not statistically significant at 1-month follow-up compared with before treatment (P>0.05). Compared with the pre-treatment, the ISI, BDI, BAI, and TCM symptom scale scores of the treatment group were lower after treatment and at 1-month follow-up (P<0.05), and the differences with the control group at the same time point were statistically significant (P<0.05). The differences in ISI, BDI, BAI, and TCM symptom scale scores of the control group before treatment, after treatment, and at 1-month follow-up were not statistically significant (P>0.05). After treatment, the serum E_2 level in the treatment group was significantly higher than that before treatment (P<0.05), and the difference with the control group was statistically significant (P<0.05). The difference in the serum E_2 level before and after treatment in the control group was not statistically significant (P>0.05). The differences in the serum FSH and LH levels between before and after treatment were not statistically significant in either group of subjects (P>0.05).

Conclusion: Kidney-tonifying and mind-calming acupuncture therapy can improve sleep quality, relieve anxiety and depression, delay the decrease of serum E_2 level, and improve related TCM symptoms in patients with PMI.

Keywords: Acupuncture Therapy; Kidney-tonifying and Mind-calming; Insomnia; Anxiety; Depression; Perimenopause; Female

First Author: YANG Wenjia, M.D., associate chief physician
Corresponding Author: CHEN Yunfei, M.D., chief physician.
E-mail: icyf1968@163.com

【摘要】**目的:** 观察“补肾安神”针刺疗法对围绝经期失眠(PMI)患者睡眠、情绪、性激素水平及中医症状的影响。**方法:** 将90例PMI患者随机分为治疗组和对照组, 每组45例。治疗组予以针刺肾俞、太溪、百会和安眠治疗; 对照组给予假针刺治疗。两组均每周治疗3次, 共4周。治疗前、治疗后及治疗结束1月后采用匹兹堡睡眠质量指数(PSQI)量表和失眠严重指数(ISI)量表评价受试者睡眠情况; 采用BECK抑郁量表(BDI)、BECK焦虑量表(BAI)评价受试者的抑郁和焦虑情绪; 采用中医证候量表评价受试者的中医症状。治疗前后检测受试者血清雌二醇(E_2)、卵泡刺激素(FSH)和促黄体生成激素(LH)水平。**结果:** 研究过程中治疗组脱落2例, 对照组无脱落。与治疗前相比, 治疗组治疗后及随访1个月时的PSQI评分显著降低(P<0.05), 与对照组相比差异有统计学意义(P<0.05)。对照组治疗后PSQI评分较治疗前显著降低(P<0.05), 随访1个月与治疗前差异无统计学意义(P>0.05)。与治疗前相比, 治疗组治疗后及随访1个月时的ISI、BDI、BAI评分和中医证候量表评分均降低(P<0.05), 与同时间点对照组差异有统计学意义(P<0.05)。对照组治疗前、治疗后及随访1个月的ISI、BDI、BAI评分和中医证候量表评分差异均无统计学意义(P>0.05)。治疗后, 治疗组血清E_2较治疗前显著升高(P<0.05), 与对照组差异有统计学意义(P<0.05)。对照组治疗前后血清E_2水平差异无统计学意义(P>0.05)。两组受试者治疗前后血清FSH和LH水平差异均无统计学意义(P>0.05)。**结论:** “补肾安神”针刺疗法治疗PMI患者能改善睡眠质量, 缓解焦虑及抑郁情绪, 延缓血清E_2水平的降低, 改善相关中医症状。

【关键词】针刺疗法; 补肾安神; 失眠症; 焦虑; 抑郁; 围绝经期; 女性

【中图分类号】R246.6　　【文献标志码】A

Perimenopause is a period from two years before menopause to one year after menopause[1]. Perimenopausal women may have a series of symptoms due to the gradual decline of ovarian function, and insomnia is one of the most common clinical symptoms[2]. Perimenopausal insomnia (PMI) seriously affects the quality of life of perimenopausal women. Studies show that the incidence of PMI in China accounts for 69.39%, and it is one of the three chief complaints of perimenopausal women[3]. At present, menopausal hormone therapy (MHT) and sedatives and hypnotics are commonly used in the clinical treatment of PMI, but there are certain adverse reactions. For example, MHT may increase the risk of gynecological cancer[4-5]. Sedatives and hypnotics have problems such as tolerance, dependence and withdrawal, residual daytime sedation, risk of recurrent insomnia, memory and cognitive impairments, and motor incoordination-related falls in the aged[6]. Therefore, there is an urgent need to find effective and safe treatments for PMI.

Clinical studies have confirmed that acupuncture has a significant effect on PMI[7-8]. Our previous clinical research results also showed that acupuncture could significantly improve the clinical symptoms of PMI patients without adverse reactions[9]. On the basis of previous research, with the principle of “treating from the kidney and treating both the tip and root”, we selected Shenshu (BL23), Taixi (KI3), Baihui (GV20), and Anmian (Extra) to treat PMI, and observed the effects of kidney-tonifying and mind-calming acupuncture on sleep, mood, sex hormone levels, and traditional Chinese medicine (TCM) symptoms in patients with PMI.

1 Clinical Materials

1.1 Diagnostic criteria

1.1.1 Diagnostic criteria in Western medicine

The diagnostic criteria for insomnia in the third edition of the *International Classification of Sleep Disorders* (ICSD-3)[10] were used in conjunction with the staging criteria for perimenopause issued by the Stages of Reproductive Aging Workshop (STRAW)[11].

1.1.2 Diagnostic criteria for TCM symptoms

Referred to the diagnostic criteria for TCM pattern of kidney Yin deficiency established in the *Guiding Principles for Clinical Study of New Chinese Medicines*[12].

1.2 Inclusion criteria

Female, aged 40-60 years; in accordance with the above Western medicine diagnostic criteria and TCM symptom diagnostic criteria; had not received acupuncture treatments; informed consent was obtained.

1.3 Exclusion criteria

Patients who used sex hormone drugs in the latest 3 months; with severe mental disorders; with severe cardiac or cerebral complications; pregnant or lactating women; were participating in other clinical trials.

1.4 Statistical analysis

The SPSS version 26.0 software was used for data analysis. The measurement data were in accordance with normal distribution and expressed as mean ± standard deviation ($\bar{x} \pm s$). The *t*-test was used for comparisons between groups, and repeated measures analysis of variance was used for comparisons between multiple time points within the group. Count data were expressed as frequencies or rates, and comparisons between groups were analyzed using the Chi-square test. P<0.05 was considered statistically significant.

1.5 General data

A total of 90 PMI subjects were included in this study, and all of them were patients who visited the Outpatient Department of Acupuncture of Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of Traditional Chinese Medicine between December 2018 and December 2021. This study was approved by the Ethics Committee of Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of

Traditional Chinese Medicine (Approval No. 2015-020). The patients were randomly divided into a control group and a treatment group by the random number table method, with 45 cases in each group. During randomization, the generation of the random number table, the inclusion of subjects, and the evaluation of the scales were completed independently by different researchers. In the treatment group, the youngest was 40 years old, and the oldest was 60. The shortest course of disease was 6 months, and the longest was 21 months. In the control group, the youngest was 40 years old, and the oldest was 59. The disease duration ranged from 5 months to 19 months. There was no significant difference in the general data between the two groups (P>0.05), showing comparability. See Table 1.

During the trial, 2 cases withdrew, and 43 cases completed the trial in the treatment group, while 45 cases completed the trial in the control group. A total of 88 cases were finally included in the statistical analysis. The flow of the trial is shown in Figure 1.

Table 1 Comparison of general data between the two groups

Group	n	Age/year ($\bar{x}$ ±s)	Duration/month ($\bar{x}$ ±s)
Treatment	43	51.4±6.7	12.1±3.9
Control	45	52.2±6.2	11.8±4.2

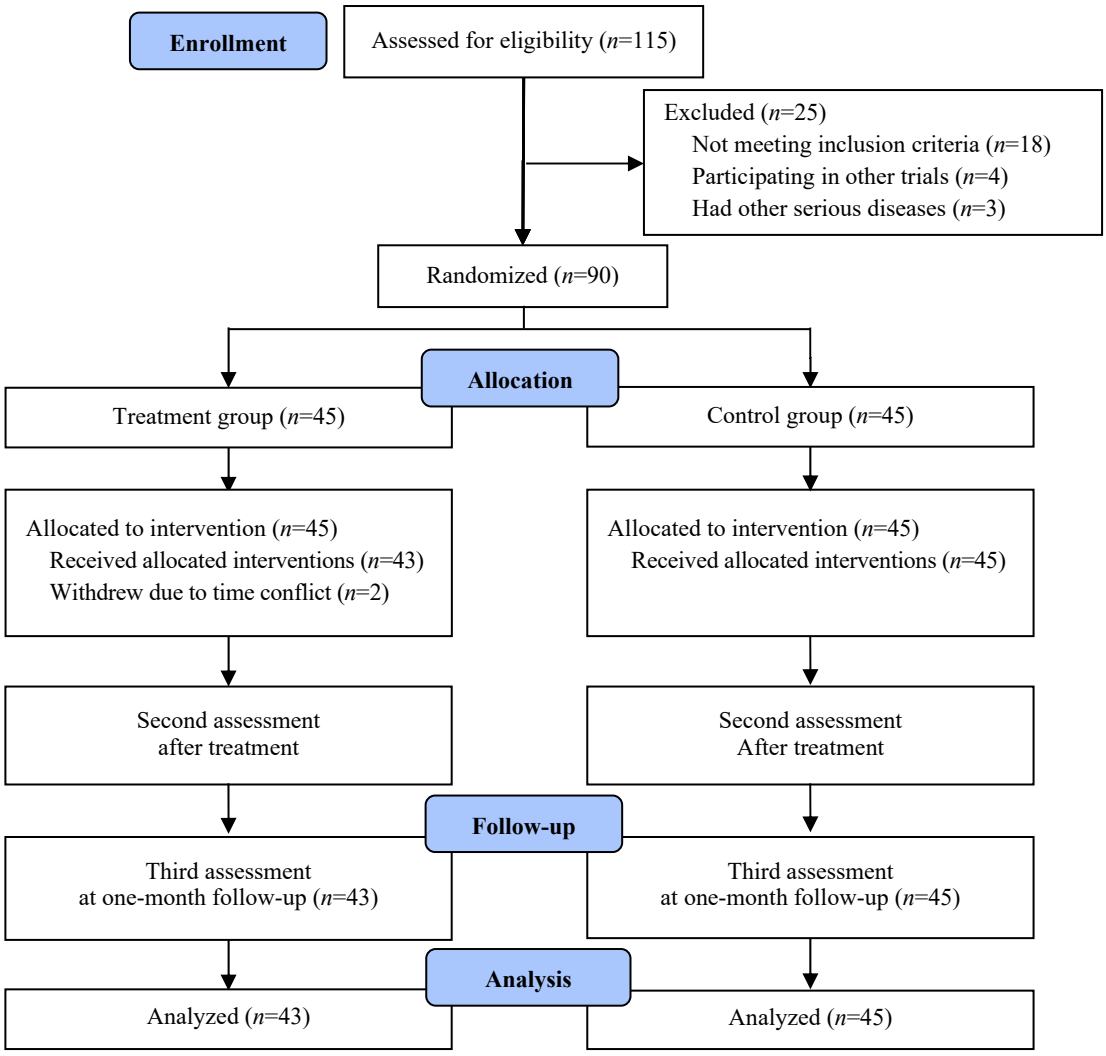

Figure 1 Flow chart of the study

2 Treatment Methods

2.1 Treatment group

The treatment group was treated with acupuncture based on the principles of kidney-tonifying and mind-calming.

Points: Baihui (GV20), bilateral Shenshu (BL23), Taixi (KI3), and Anmian (Extra)[13].

Methods: The patient took a sitting position on the treatment bed. After local skin disinfection of the points, disposable sterile acupuncture needles of 0.25 mm in diameter and 40 mm in length were used for needling. Shenshu (BL23) was inserted 10-15 mm at an angle of 15° toward the spine, and the patient was assisted to lie down slowly by holding the handle of the needle after insertion; Baihui (GV20) was inserted subcutaneously by a depth of 10-15 mm; Taixi (KI3) and Anmian (Extra) were inserted perpendicularly by a depth of 10-15 mm, and the positioning of the points is shown in Figure 2. After the needles were inserted to obtain the needling sensation (Deqi), the balanced reinforcing and reducing manipulation was performed. The needles were retained for 30 min. The patient was treated 3 times per week for 4 weeks in total.

2.2 Control group

The control group was treated with sham acupuncture by shallow needling at sham points[14].

Sham points: Sham Baihui (GV20) and bilateral sham Shenshu (BL23), sham Taixi (KI3), and sham Anmian (Extra) were taken. The position of sham Shenshu (BL23) was 1 Cun below and beside Shenshu (BL23). The sham Taixi (KI3) was positioned 1 Cun above and 0.5 Cun beside Taixi (KI3). The sham Baihui (GV20) was positioned at the midpoint between the right and posterior Sishencong (EX-HN1). The sham Anmian (Extra) was 1 Cun below Anmian (Extra). The location of sham points is shown in Figure 2.

Methods: The patient was in a sitting position on the treatment bed. After local skin disinfection, sterile acupuncture needles of 0.25 mm in diameter and 40 mm in length were used to stimulate the sham points. The sham Shenshu (BL23) was inserted 1-2 mm at an angle of 15° toward the spine, and the patient was assisted to lie down slowly by holding the handle of the needle after insertion; sham Baihui (GV20) was inserted subcutaneously by a depth of 1-2 mm; sham Taixi (KI3) and Anmian (Extra) were inserted perpendicularly by a depth of 1-2 mm. No manipulation was performed after needle insertion to avoid needling sensation (Deqi). The treatment was given 3 times a week for 4 weeks.

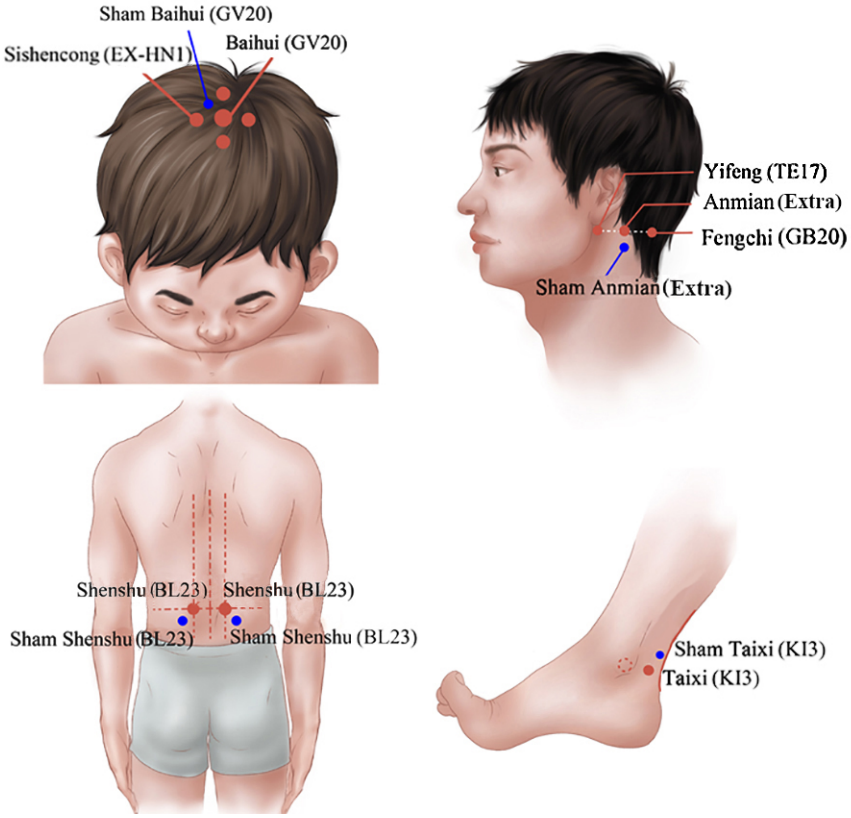

Figure 2 Localization of points and sham points

3 Outcomes Observation

3.1 Observation items

3.1.1 Primary outcome measures

Pittsburgh sleep quality index (PSQI) scale[15] was used for the subjective evaluation of patients' sleep quality; the higher the score, the worse the sleep quality.

Insomnia severity index (ISI) scale[16] was mainly used to evaluate the nature and severity of insomnia and its impact on the daytime function of patients. The more severe the insomnia, the higher the score.

The two scales were evaluated before treatment, after treatment, and at 1-month follow-up.

3.1.2 Secondary outcome measures

Beck depression inventory (BDI) was used to evaluate the depression of subjects[17]. Generally, the total score of BDI greater than or equal to 15 points is used as the judgment of positive depression.

Beck anxiety inventory (BAI) was used to evaluate the anxiety of subjects[18]. Generally, the total score of BAI greater than or equal to 45 points is used as the judgment of positive anxiety.

TCM symptom scale was used to evaluate the TCM symptoms of patients. It consists of 7 parts, including 2 main symptoms, 4 secondary symptoms, tongue manifestations, and pulse conditions. No symptoms, scored 0 points; 1 point, if the symptoms occur rarely and can be relieved spontaneously; 2 points, if the symptoms can be controlled and relieved quickly after taking medicine; symptoms occur frequently and severely affect normal work and life, 3 points.

The above scales were evaluated before treatment, after treatment, and at 1-month follow-up.

The serum sex hormone levels of estradiol (E_2), follicle-stimulating hormone (FSH), and luteinizing hormone (LH) were detected by the chemiluminescence method before and after treatment.

3.2 Results

3.2.1 Comparison of the PSQI score between the two groups at different time points

There was no statistically significant difference in the PSQI score between the two groups before treatment (P>0.05). The PSQI score of all subjects showed a time effect with the progression of the treatment (P<0.05), indicating that the PSQI score changed significantly with time. The comparison of PSQI score in both two groups showed a group effect (P<0.05), indicating that different treatment methods could significantly affect the PSQI score of patients. There was an interaction effect between group and time (P<0.05), indicating that the changing trend of PSQI score was different due to different treatment methods over time.

The PSQI score of the treatment group after intervention and at the 1-month follow-up was significantly lower than that before treatment (P<0.05), and the scores at the two time points were significantly different from those of the control group (P<0.05). In the control group, the PSQI score after treatment was significantly lower than that before treatment (P<0.05), but there was no significant difference in PSQI score at 1-month follow-up compared with that before treatment (P>0.05). See Table 2 for details.

3.2.2 Comparison of the ISI score between the two groups at different time points

There was no statistically significant difference in the ISI score between the two groups before treatment (P>0.05). The ISI score of all subjects showed a time effect with the progression of treatment (P<0.05), indicating that the ISI score would change significantly with time. There was a group effect in the overall comparison of ISI score in the two groups (P<0.05), indicating that different treatment methods could significantly affect the ISI score of patients. There was an interaction effect between group and time (P<0.05), indicating that the changing trend of ISI score over time would be different due to different treatment methods.

The ISI score of the treatment group after intervention and at the 1-month follow-up was significantly lower than that before treatment (P<0.05), and the scores at the two time points were significantly different from those of the control group (P<0.05). There was no statistically significant difference in the ISI score before treatment, after treatment, and at 1-month follow-up in the control group (P>0.05). See Table 3 for details.

3.2.3 Comparison of the BDI score between the two groups at different time points

There was no statistically significant difference in the BDI score between the two groups before treatment (P>0.05). The BDI score of all subjects showed a time effect with the treatment process (P<0.05), indicating that the BDI score would change significantly with time. There was a group effect in the overall comparison of BDI score in the two groups (P<0.05), indicating that different treatment methods could significantly affect the BDI score of patients. There was an interaction effect between group and time (P<0.05), indicating that the changing trend of BDI score over time would be different due to different treatment methods.

The BDI score of the treatment group after treatment and at the 1-month follow-up was significantly lower than that before treatment (P<0.05), and the score at each time point was significantly different from that of the control group (P<0.05). In the control group, there was no statistically significant difference in the BDI score before treatment, after treatment, and at 1-month follow-up (P>0.05). See Table 4 for details.

Table 2 Results of the repeated measures analysis of variance of the PSQI score in the two groups ($\bar{x}$ ±*s*) Unit: point

Group	*n*	Before treatment	After treatment	1-month follow-up
Treatment	43	17.35±2.11	13.70±3.02[1)2)]	13.81±1.94[1)2)]
Control	45	17.40±2.10	16.31±1.47[1)]	16.58±1.84
Intervention		*F*=12.417, *P*<0.001		
Time		*F*=37.038, *P*<0.001		
Intervention * Time interaction		*F*=40.310, *P*<0.001		

Note: PSQI=Pittsburgh sleep quality index; compared with the same group before treatment, 1) *P*<0.05; compared with the control group at the same time point, 2) *P*<0.05.

Table 3 Results of the repeated measures analysis of variance of the ISI score in the two groups ($\bar{x}$ ±*s*) Unit: point

Group	*n*	Before treatment	After treatment	1-month follow-up
Treatment	43	22.30±3.48	13.95±3.22[1)2)]	14.35±4.04[1)2)]
Control	45	22.82±3.83	21.64±3.28	21.66±3.34
Intervention		*F*=28.796, *P*<0.001		
Time		*F*=51.109, *P*<0.001		
Intervention * Time interaction		*F*=94.369, *P*<0.001		

Note: ISI=Insomnia severity index; compared with the same group before treatment, 1) *P*<0.05; compared with the control group at the same time point, 2) *P*<0.05.

Table 4 Results of the repeated measures analysis of variance of the BDI score in the two groups ($\bar{x}$ ±*s*) Unit: point

Group	*n*	Before treatment	After treatment	1-month follow-up
Treatment	43	15.79±5.60	10.93±5.11[1)2)]	10.02±2.35[1)2)]
Control	45	15.84±6.88	14.89±5.45	13.78±1.04
Intervention		*F*=6.156, *P*<0.001		
Time		*F*=21.084, *P*<0.001		
Intervention * Time interaction		*F*=12.230, *P*<0.001		

Note: BDI=Beck depression inventory; compared with the same group before treatment, 1) *P*<0.05; compared with the control group at the same time point, 2) *P*<0.05.

3.2.4 Comparison of the BAI score between the two groups at different time points

There was no significant difference in the BAI score between the two groups before treatment (*P*>0.05). The BAI score of all subjects showed a time effect (*P*<0.05), indicating that the BAI score would change with the treatment process significantly with time. The overall comparison of BAI score in the two groups showed a group effect (*P*<0.05), indicating that different treatment methods could significantly affect the BAI score of patients. There was an interaction effect between group and time (*P*<0.05), indicating that the changing trend of BAI score over time was different due to different treatment methods.

The BAI score of the treatment group after treatment and at the 1-month follow-up was significantly lower than that before treatment (*P*<0.05), and there was a significant difference between the treatment group and the control group at each time point (*P*<0.05). In the control group, there was no significant difference in the BAI score before treatment, after treatment, and at 1-month follow-up (*P*>0.05). See Table 5 for details.

3.2.5 Comparison of the TCM symptom scale score between the two groups at different time points

There was no statistically significant difference in the TCM symptom scale score between the two groups before treatment (*P*>0.05). There was a time effect in the comparison of the TCM symptom scale score over the treatment process (*P*<0.05), indicating that TCM symptom scale score would change significantly with time. The overall comparison of TCM symptom scale score in the two groups showed a group effect (*P*<0.05), indicating that different treatment methods could significantly affect the TCM symptom scale score. There was an interaction effect between group and time (*P*<0.05), indicating that the changing trend of TCM symptom scale score over time would be different due to the different treatment methods.

The TCM symptom scale score after treatment and at the 1-month follow-up in the treatment group was significantly lower than that before treatment (P<0.05), and the scores at the two time points were significantly different from those in the control group (P<0.05). There was no statistically significant difference in the TCM symptom scale score before treatment, after treatment, and at 1-month follow-up in the control group (P>0.05). See Table 6 for details.

3.2.6 Comparison of the serum sex hormone levels between the two groups before and after treatment

Before treatment, there were no statistically significant differences in the serum LH, FSH, and E_2 levels between the two groups (P>0.05). After treatment, the serum E_2 level in the treatment group was significantly higher than that before treatment (P<0.05), and the difference was statistically significant compared with the control group (P<0.05). There was no significant difference in E_2 before and after treatment in the control group (P>0.05). After treatment, there was no significant change in the serum LH and FSH levels in either group (P>0.05), and there was no significant difference between the two groups (P>0.05). See Table 7 for details.

3.2.7 Safety evaluation

During the treatment, there were no cases of dizziness, broken needles, or infection in the two groups.

Table 5 Results of the repeated measures analysis of variance of the BAI score in the two groups ($\bar{x}$ ±s) Unit: point

Group	n	Before treatment	After treatment	1-month follow-up
Treatment	43	32.02±7.87	25.88±3.86[1)2)]	24.81±3.69[1)2)]
Control	45	33.82±10.40	30.96±4.67	32.13±4.01
Intervention		F=3.842, P<0.001		
Time		F=12.407, P<0.001		
Intervention * Time interaction		F=26.944, P=0.025		

Note: BAI=Beck anxiety inventory; compared with the same group before treatment, 1) P<0.05; compared with the control group, 2) P<0.05.

Table 6 Results of the repeated measures analysis of variance of the TCM symptom scale score in the two groups ($\bar{x}$ ±s) Unit: point

Group	n	Before treatment	After treatment	1-month follow-up
Treatment	43	5.51±1.04	3.90±0.77[1)2)]	4.00±0.71[1)2)]
Control	45	5.52±1.21	5.27±1.13	5.12±0.79
Intervention		F=23.298, P<0.001		
Time		F=28.876, P<0.001		
Intervention * Time interaction		F=46.892, P<0.001		

Note: Compared with the same group before treatment, 1) P<0.05; compared with the control group, 2) P<0.05.

Table 7 Comparison of serum sex hormones before and after treatment in the two groups ($\bar{x}$ ±s)

Item	Control group (n=45)		Treatment group (n=43)	
	Before treatment	After treatment	Before treatment	After treatment
LH/(mIU·mL^{-1})	25.33±12.84	27.54±12.15	25.50±13.22	22.78±11.89
FSH/(mIU·mL^{-1})	54.64±27.76	58.51±21.25	50.81±34.76	47.89±30.42
E_2/(pg·mL^{-1})	13.62±6.98	14.27±7.03	13.77±7.97	21.44±10.78[1)2)]

Note: LH=Luteinizing hormone; FSH=Follicle-stimulating hormone; E_2=Estradiol; compared with the same group before treatment, 1) P<0.05; compared with the control group, 2) P<0.05.

4 Discussion

PMI belongs to the categories of “symptoms before and after menopause” and “insomnia” in TCM. When a woman reaches the perimenopausal period, her kidney essence gradually fails, her Tian Gui is insufficient, and the Thoroughfare Vessel and Conception Vessel are feeble, resulting in insufficient essence and blood and irregular menstruation. And women consume more blood throughout their life, which is the state that

"Yin is often insufficient, and Yang is often in excess"[19]. Therefore, the mechanism of this disease is mostly deficiency of kidney Yin, and Yin and Yang are imbalanced in the body, which triggers the dysfunction of organs in the whole body, resulting in a variety of symptoms, including insomnia[20-21]. In this study, the treatment principle is to tonify the kidney and calm the mind, and Shenshu (BL23), Taixi (KI3), Baihui (GV20), and Anmian (Extra) were selected and given acupuncture treatment. Shenshu (BL23) is the back-Shu point of the kidney, and Tian Gui is hidden in the kidney, so Shenshu (BL23) can secure the innate essence[22]. At the same time, the Bladder Meridian enters the brain and is closely related to the brain marrow, so acupuncture at Shenshu (BL23) can regulate brain function and help to calm the mind[23]. Taixi (KI3) is the Shu-stream point and Yuan-primary point of the Kidney Meridian and can replenish kidney Yin[24]. Baihui (GV20) is located at the top of the summit and is mainly used to treat spirit diseases. It is at the center of the head and can effectively regulate the brain and spirit functions, thereby can treat insomnia[25]. Anmian (Extra) is an extra point that can regulate the operation of meridian Qi in the Yin Heel Vessel and Yang Heel Vessel, and it is one of the special points for the treatment of insomnia[26]. Shenshu (BL23), Taixi (KI3), Baihui (GV20), and Anmian (Extra) are used together to treat both the symptoms and the root cause of insomnia, and they work together to tonify the kidney and calm the mind.

Modern medicine believes that due to ovarian failure, the level of estrogen in perimenopausal women will decrease sharply, which leads to a decrease in the regulation function of estrogen in the central nervous system, and thus insomnia happens[2]. E_2 is the major form of estrogen. The E_2 level decreases rapidly during perimenopause and thus leads to several changes in the brain that have an impact on sleep, mood, and cognition[27]. Studies have found that E_2 levels are inversely related to sleep problems, and the decreased E_2 is associated with difficulty falling asleep and multiple awakenings[28-29]. Perimenopausal women's sleep changes are often characterized by subjective complaints such as difficulty falling asleep, difficulty maintaining asleep, and inability to resume sleep after sleep interruption, which can lead to severe daytime symptoms, including inattention and mood disturbances[30]. Insomnia is one of the sources of perimenopausal distress in women and has a significant impact on patients' quality of life, mood, productivity, and physical health[31-32]. This sleep disorder is strongly associated with an increased risk of cardiovascular diseases, depression, diabetes, and neurobehavioral disorders[33-34]. At the same time, decreased ovarian estrogen secretion is also a high-risk factor for emotional disorders[35]. Perimenopause is a window of vulnerability to the development of depressive symptoms and major depressive episodes[36-38]. The incidence of perimenopausal depressive symptoms is high[39-40]. It has been clinically confirmed that estrogen therapy can improve perimenopausal emotional disorders[41]. In addition, animal experiments have also confirmed that estrogen treatment can improve the symptoms of depression and anxiety in perimenopausal rat models[42]. These have revealed a close relationship between estrogen and mood disorders[43].

This study aims to evaluate the clinical efficacy of kidney-tonifying and mind-calming acupuncture in the treatment of PMI from the aspects of sex hormone levels, sleep, mood, and TCM symptoms. The results showed that kidney-tonifying and mind-calming acupuncture could significantly reduce the PSQI score and ISI score of patients with PMI and improve the symptoms of insomnia. It can reduce the TCM symptom scale score and improve the TCM symptoms of patients. It can reduce the scores of anxiety and depression scales and improve the mood of patients. E_2 can activate sleep-promoting neurons in the hypothalamus, the sleep center, through E_2 receptors, and decreased E_2 reduces the activation of sleep-promoting neurons, leading to the occurrence of insomnia[44-46]. The results of this study showed that acupuncture therapy could increase the serum E_2 level in patients with PMI. It is suggested that kidney-tonifying and mind-calming acupuncture therapy may improve the sleep, mood, and TCM symptoms of PMI patients with kidney Yin deficiency by improving the regulation function of E_2 in the sleep center. The control group was treated with sham acupuncture. The results showed that sham acupuncture could reduce the PSQI score of the subjects to a certain extent after treatment, but the PSQI score of the treatment group was significantly lower than that of the control group, suggesting that sham acupuncture had a certain improvement effect on insomnia symptoms in patients with PMI, but the effect of real acupuncture was better and lasting.

In conclusion, the results of this study indicate that kidney-tonifying and mind-calming acupuncture therapy can improve sleep quality, mood, and TCM symptoms, increase the serum E_2 level, and have a significant clinical effect on PMI patients with kidney Yin deficiency. However, the number of cases included in this study was small. In the future, the sample size will be increased, and multi-center large-sample randomized controlled trials will be carried out to reduce the influence of sample differences on the results, so as to further explore the mechanism of acupuncture in improving PMI.

Conflict of Interest

The authors declare that there is no potential conflict of interest in this article.

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Statement of Informed Consent

Informed consent was obtained from all individual participants.

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Translator: KONG Xiehe (孔谐和)

