

# Effect of acupuncture and moxibustion combined with modified Yangxin Anshen decoction on insomnia in cancer patients undergoing radiotherapy

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## ABSTRACT

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**Keywords:** Acupuncture therapy, Chinese traditional, sleep initiation and maintenance disorders, radiotherapy, neoplasms, sleep quality.

**Background:** To evaluate the effect of acupuncture and moxibustion combined with modified Yangxin Anshen Decoction on insomnia in cancer patients with heart and spleen deficiency during external beam radiotherapy. **Materials and Methods:** Seventy adult cancer patients receiving radiotherapy were randomly assigned to an intervention group (n=35) or a control group (n=35). The intervention group received acupuncture, moxibustion, and modified Yangxin Anshen Decoction during the radiotherapy course, whereas the control group received the decoction alone. Sleep quality and emotional status before the start and at the end of radiotherapy were assessed using various sleep quality monitoring systems as well as depression scales. Cerebral blood flow was evaluated by transcranial Doppler ultrasonography. **Results:** Both groups showed reduced PSQI scores at the end of radiotherapy compared with baseline (P<0.05). However, the intervention group had shorter sleep latency, higher sleep efficiency, fewer disturbances, longer sleep duration, less daytime dysfunction, reduced hypnotic use, and better subjective sleep quality than the control group (P<0.05). The intervention group exhibited longer total sleep time, a higher proportion of deep sleep, and fewer nocturnal awakenings compared with the control group (P<0.05 or P<0.01). Sleep latency was significantly shorter (P<0.001), and cerebral blood flow indices were significantly improved (P<0.01) in the intervention group. **Conclusion:** Acupuncture and moxibustion combined with modified Yangxin Anshen Decoction administered during radiotherapy can significantly improve insomnia, alleviate radiotherapy-related emotional distress, and enhance cerebral blood flow in cancer patients, providing a valuable integrative approach for managing sleep disorders during radiotherapy.

## INTRODUCTION

Insomnia, a debilitating sleep disorder characterized by difficulty initiating or maintaining sleep, significantly impacts sleep satisfaction and daytime functioning<sup>(1, 2)</sup>. In cancer patients undergoing radiotherapy, insomnia is a prevalent and severe issue, driven by the multifaceted physical and psychological stressors associated with radiation treatment<sup>(3)</sup>. Radiotherapy, a critical modality in cancer management, targets malignant cells but often induces side effects such as fatigue, pain, anxiety, and neurovascular changes, all of which exacerbate sleep disturbances<sup>(4)</sup>. In the context of Traditional Chinese Medicine (TCM), insomnia in these patients is frequently linked to heart and spleen deficiency, where imbalances in qi and blood disrupt yin-yang harmony, intensifying radiotherapy-related sleep challenges<sup>(5)</sup>. The resulting insomnia leads to mental fatigue, emotional distress, and reduced quality of life, which can compromise treatment adherence and overall prognosis<sup>(6)</sup>. Addressing insomnia in radiotherapy patients is thus essential to mitigate the

compounded burden of cancer treatment and improve clinical outcomes. Epidemiological studies have shown that a substantial proportion of patients receiving radiotherapy report moderate-to-severe sleep disturbances, underscoring the need for safe and effective interventions that can be used concurrently with oncologic treatment<sup>(7, 8)</sup>.

Radiotherapy's impact on sleep is multifaceted, involving direct physiological effects such as inflammation and oxidative stress, as well as psychological factors like anxiety over treatment outcomes<sup>(9)</sup>. These disturbances are particularly pronounced in patients with heart and spleen deficiency, who exhibit symptoms such as restlessness, palpitations, and fatigue, further aggravated by radiation-induced systemic stress<sup>(10, 11)</sup>. Conventional treatments, such as sedative-hypnotic drugs, are often employed to manage insomnia but pose risks of dependency, cognitive impairment, and interactions with cancer therapies, making them less suitable for radiotherapy patients<sup>(12)</sup>. TCM offers a promising alternative through interventions like acupuncture and herbal decoctions,

which address both the physiological and emotional aspects of insomnia with minimal side effects<sup>(13)</sup>. Acupuncture, known for its ability to regulate autonomic nervous system activity and enhance cerebral blood flow, has shown efficacy in alleviating sleep disturbances<sup>(14)</sup>. The Yangxin Anshen Decoction, tailored to heart and spleen deficiency, nourishes vital organs and calms the mind, potentially counteracting radiotherapy's disruptive effects on sleep<sup>(15)</sup>. Previous clinical studies and experimental investigations have suggested that acupuncture and related TCM herbal prescriptions can improve sleep quality, reduce anxiety and depression, and modulate neuroendocrine function in patients with primary insomnia and insomnia secondary to chronic diseases<sup>(16-19)</sup>. However, evidence targeting insomnia specifically in cancer patients undergoing radiotherapy, especially those with heart and spleen deficiency, remains limited.

Based on this background, the present study was designed to evaluate the efficacy of acupuncture and moxibustion combined with modified Yangxin Anshen Decoction in improving sleep quality, reducing negative emotions, and enhancing cerebral blood flow in cancer patients with insomnia of heart and spleen deficiency type undergoing external beam radiotherapy. By targeting the unique interplay of radiotherapy-induced stressors and TCM-defined deficiencies, the intervention aims to restore sleep architecture and emotional balance while remaining compatible with ongoing oncologic treatment.

The novelty of this study lies in its focus on radiotherapy-related insomnia in cancer patients, a population that has been less frequently examined in previous acupuncture and TCM sleep studies. Unlike prior research that has generally addressed primary insomnia or heterogeneous insomnia populations, this randomized controlled trial investigates a tailored intervention for patients receiving definitive radiotherapy, and it combines subjective sleep and emotion scales with objective mattress-based sleep monitoring and transcranial Doppler assessment of cerebral blood flow. By integrating acupuncture's neuroregulatory and circulatory effects with the organ-nourishing and mind-calming properties of a modified Yangxin Anshen Decoction, this study proposes a comprehensive, low-risk strategy to mitigate radiotherapy's impact on sleep and mood, thereby potentially improving treatment tolerance and overall quality of life and providing a basis for further integration of TCM into supportive oncology care.

## MATERIALS AND METHODS

### *Research objects and data acquisition*

Seventy cancer patients diagnosed with insomnia of heart and spleen deficiency type, undergoing

radiotherapy at the Acupuncture Department of Xiangtan Chinese Medicine Hospital (Xiangtan, China) from June 2019 to June 2021, were enrolled. All patients had pathologically confirmed solid tumors, mainly breast cancer, lung cancer, and head and neck cancers, and developed new-onset or clearly aggravated insomnia after the start of external beam radiotherapy. All participants provided informed consent, and the study was approved by the hospital's ethics committee (Approval No. XTCMH-2019-032). Patients were randomly assigned to an intervention group (n = 35) receiving acupuncture, moxibustion, and modified Yangxin Anshen Decoction, and a control group (n = 35) receiving only the decoction. Randomization was performed using a computer-generated random number table created with Microsoft Excel 2019 (Microsoft Corporation, USA).

The inclusion criteria were as follows: patients aged 18–60 years; diagnosed with cancer and actively receiving external beam radiotherapy; meeting both TCM and Western medicine diagnostic criteria for insomnia with heart and spleen deficiency; having an insomnia duration of 1–3 months; a Pittsburgh Sleep Quality Index (PSQI) score  $\geq 7$ ; no major systemic diseases unrelated to cancer; and willingness to participate with good compliance to the treatment protocols.

Exclusion criteria included: age outside the range of 18–60 years; severe primary diseases such as hematopoietic disorders or other serious organ dysfunction; poor adherence to the treatment or radiotherapy protocols; pregnancy or breastfeeding; known allergy to any study medication or acupuncture materials; and diagnosed mental illness unrelated to cancer or its treatment.

### *Radiotherapy protocol*

All patients underwent radiotherapy using a Varian TrueBeam Linear Accelerator (Varian Medical Systems, Palo Alto, USA) at Xiangtan Chinese Medicine Hospital. Radiotherapy was administered for various cancer types, predominantly breast, lung, and head and neck cancers, with a total dose ranging from 40 to 60 Gy, delivered in 2 Gy fractions, 5 days per week, over 4-6 weeks. Treatment planning was conducted using the Eclipse Treatment Planning System (Varian Medical Systems, Palo Alto, USA). Patients received either intensity-modulated radiotherapy (IMRT) or three-dimensional conformal radiotherapy (3D-CRT), depending on tumor characteristics and clinical requirements. Radiation fields were verified daily using cone-beam computed tomography (CBCT) integrated with the TrueBeam system.

### *Intervention methods*

All study interventions were initiated within the first week after the start of radiotherapy and were

continued throughout the entire radiotherapy course; no patient received the study intervention before radiotherapy began or after radiotherapy was completed.

Intervention group (acupuncture + moxibustion + decoction): Patients in the intervention group received acupuncture, moxibustion, and modified Yangxin Anshen Decoction concurrently with radiotherapy. Acupuncture was performed using sterile, single-use stainless steel needles (Huatuo, Suzhou Medical Appliance Factory, Suzhou, China; 0.25 mm diameter, 25–50 mm length). The selected acupoints included Baihui (GV20), Sishencong (EX-HN1), Xinshu (BL15), Pishu (BL20), Sanyinjiao (SP6), Zusanli (ST36), Shenmai (BL62), Zhaohai (KI6), and Anmian (EX-HN22). \*\*After skin disinfection with 75% ethanol (Sinopharm Chemical Reagent Co., Shanghai, China), the needles were inserted using flat acupuncture at Baihui and Sishencong (10–15 mm depth), oblique puncture at Xinshu and Pishu (15–20 mm depth), and straight puncture at Sanyinjiao, Zusanli, Shenmai, Zhaohai, and Anmian (20–50 mm depth). A mild reinforcing (twirling supplement) method was applied to achieve a comfortable needling sensation. Each treatment session lasted approximately 30 minutes and was performed once every two days, with a total of 10 sessions constituting one treatment course. Patients completed three consecutive courses (30 sessions in total) over about 6 weeks, synchronized with the radiotherapy schedule.

Moxibustion was applied using moxa sticks (Huatuo, Suzhou Medical Appliance Factory, Suzhou, China) at Xinshu and Pishu to warm yang and promote qi and blood circulation. During each acupuncture session, the ignited moxa stick was held 2–3 cm above the skin surface at the selected acupoints, and gentle warmth was maintained for approximately 10 minutes per point, avoiding skin burns or discomfort.

The Yangxin Anshen Decoction was prepared daily using a decoction machine (YJ20/1+1, Beijing Donghuayuan Medical Equipment Co., Beijing, China). The main prescription included mulberries (15 g), wild jujube kernels (15 g), baiziren (15 g), *Salvia miltiorrhiza* (15 g), *Tengjiao* vine (30 g), *Albizia julibrissin* (30 g), and *Schisandra chinensis* (10 g), all sourced from Tongrentang Pharmaceutical Co. (Beijing, China). The herbs were decocted in 500 mL of water to yield approximately 200 mL of liquid, which was taken once daily in two divided doses (morning and evening). According to individual radiotherapy-related symptoms, the prescription was modified as follows: *Shanzhi* (10 g, Tongrentang, Beijing, China) was added for sore throat; *Tribulus terrestris* (15 g) and *Prunella vulgaris* (15 g, Tongrentang, Beijing, China) were added for hypertension; *Gorgon* seed (15 g) and *dodder* (15 g, Tongrentang, Beijing, China) were added for

nocturnal polyuria; and calcined corrugated seed (10 g, Tongrentang, Beijing, China) was added for excessive gastric acid. Each decoction treatment course lasted 10 days, and patients completed three consecutive courses during radiotherapy.

Control group (decoction only): Patients in the control group received only the Yangxin Anshen Decoction, prepared and modified as described for the intervention group. The decoction was administered once daily for three consecutive 10-day courses, starting within the first week of radiotherapy and continuing in parallel with the radiotherapy course. No acupuncture or moxibustion was performed in the control group.

### Diagnostic criteria

Western medicine diagnostic criteria for insomnia were based on difficulty in initiating or maintaining sleep, or experiencing non-restorative sleep, occurring more than three times per week for longer than one month, with resulting daytime fatigue, reduced attention, and decreased functional efficiency. In this study, special attention was paid to insomnia that appeared or worsened after the initiation of radiotherapy, and that significantly affected sleep satisfaction and social functioning in the context of radiotherapy-related stress, while excluding insomnia caused by non-radiotherapy-related physical or mental illnesses.

TCM diagnostic criteria for heart and spleen deficiency insomnia were established according to standard TCM guidelines and included difficulty falling asleep or maintaining sleep, insufficient sleep duration with frequent awakenings, palpitations, forgetfulness, fatigue, poor appetite, and pale tongue with a thin pulse. These symptoms were considered in association with radiotherapy side effects, such as fatigue and emotional instability, and the pattern was diagnosed when the overall clinical picture indicated heart and spleen deficiency as the primary syndrome type.

### Observation indicators

Sleep quality and related psychological and physiological parameters were assessed using standardized scales and monitoring equipment. The Pittsburgh Sleep Quality Index (PSQI) was used to evaluate multiple dimensions of sleep, including sleep latency, sleep efficiency, sleep disturbances, sleep duration, daytime dysfunction, use of hypnotic medication, and subjective sleep quality<sup>(1)</sup>. The Athens Insomnia Scale (AIS) was applied to quantify insomnia severity on a 0–3 scale, with higher scores indicating more severe insomnia<sup>(2)</sup>. Emotional status was assessed using the Hamilton Depression Scale (HAMD) and the Self-Rating Depression Scale (SDS), which measure the severity of depressive symptoms<sup>(3, 4)</sup>. Daytime sleepiness was evaluated with the Epworth Sleepiness Scale (ESS)<sup>(5)</sup>. The Dysfunctional

Beliefs and Attitudes about Sleep Scale (DBAS) was employed to assess maladaptive sleep-related cognitions<sup>(6)</sup>.

Objective sleep parameters, including sleep latency, number of nocturnal awakenings, total sleep time, and proportion of deep sleep, were recorded using a mattress sleep monitoring system (SleepSense Mattress Monitor, SleepSense, Illinois, USA). Patients also completed daily sleep logs to record subjective total sleep time and the number of awakenings. TCM syndrome scores for heart and spleen deficiency insomnia (e.g., restlessness, palpitations, fatigue, and poor appetite) were evaluated according to the 2002 Clinical Guidelines for New Drugs of Traditional Chinese Medicine<sup>(7)</sup>. Cerebral blood flow was assessed using transcranial Doppler ultrasonography with the EMS-9PB Transcranial Doppler System (Delica, Shenzhen, China), measuring peak systolic velocity (Vp), end-diastolic velocity (Vd), and resistance index (RI) in the left and right middle cerebral arteries (LMCA, RMCA), left and right vertebral arteries (LVA, RVA), and the basilar artery (BA). All measurements were performed before the start of radiotherapy and repeated at the end of the radiotherapy course after three treatment courses.

Therapeutic efficacy for insomnia was evaluated based on changes in sleep duration and clinical symptoms. "Cured" was defined as total sleep time > 6 hours per night with essentially normal sleep and refreshed awakening. "Markedly effective" indicated a substantial improvement in sleep quality with total sleep time > 3 hours and clear relief of main symptoms. "Effective" referred to mild improvement in sleep symptoms with some increase in sleep time ( $\leq 3$  hours) and partial symptom relief. "Invalid" indicated no appreciable change in sleep duration or symptoms compared with baseline. The total effective rate was calculated as the sum of cured, markedly effective, and effective cases divided by the total number of cases.

### Statistical methods

Data were processed using Microsoft Excel 2019 (Microsoft Corporation, Redmond, USA) for data entry and SAS 9.2 (SAS Institute Inc., Cary, USA) for statistical analysis. Measurement data (mean  $\pm$  SD) were compared using independent-samples or paired t-tests for normally distributed data with homogeneous variance; otherwise, non-parametric tests were applied. Enumeration data were expressed as percentages and analyzed with chi-square tests. A P-value <0.05 indicated statistical significance.

## RESULTS

### Baseline characteristics

Before the start of radiotherapy, there were no

significant differences between the two groups (35 cases each) in age, sex, body weight, smoking and drinking history, or disease duration ( $P > 0.05$ ), indicating good comparability at baseline (table 1).

**Table 1.** Baseline characteristics of cancer patients with insomnia before radiotherapy.

Project	Control group (modified Yangxin Anshen Decoction only, n = 35)	Intervention group (acupuncture + moxibustion + modified Yangxin Anshen Decoction, n = 35)	t/ $\chi^2$	P
Age (years)	42.63 $\pm$ 7.72	41.55 $\pm$ 7.80	-0.473	>0.05
Male [cases, %]	16 (45.71%)	14 (40.00%)	0.075	>0.05
Female [cases, %]	19 (54.29%)	21 (60.00%)	—	—
Weight (kg)	66.16 $\pm$ 1.25	65.94 $\pm$ 1.04	0.362	>0.05
Smoking history [cases, %]	9 (25.71%)	7 (20.00%)	0.781	>0.05
Drinking history [cases, %]	18 (51.43%)	15 (42.86%)	1.315	>0.05
Disease duration (days)	66.48 $\pm$ 12.37	65.62 $\pm$ 12.53	-0.256	>0.05

### PSQI score analysis

At baseline (before radiotherapy), PSQI scores were similar between the control and intervention groups ( $P > 0.05$ ). At the end of the radiotherapy course (after three treatment courses), PSQI scores decreased significantly in both groups ( $P < 0.05$ ), indicating improved sleep quality. The intervention group showed significantly greater reductions in sleep latency, sleep efficiency, sleep disturbances, sleep duration, daytime dysfunction, hypnotic use, and subjective sleep quality than the control group ( $P < 0.05$ ), suggesting a more pronounced improvement in overall sleep (table 2).

**Table 2.** PSQI scores before radiotherapy and at the end of radiotherapy.

Observations	Group	Before radiotherapy	End of radiotherapy	P (within group)
Sleep latency (score)	Control group	2.29 $\pm$ 0.17	1.29 $\pm$ 0.07	<0.05
	Intervention group	2.35 $\pm$ 0.15	0.73 $\pm$ 0.10	<0.05
	P (between groups)	>0.05	<0.05	—
Sleep efficiency (score)	Control group	2.37 $\pm$ 0.16	1.18 $\pm$ 0.15	<0.05
	Intervention group	2.33 $\pm$ 0.13	0.65 $\pm$ 0.14	<0.05
	P (between groups)	>0.05	<0.05	—

### AIS and ESS scores

Before radiotherapy, AIS and ESS scores did not differ significantly between the two groups ( $P > 0.05$ ). After three treatment courses, corresponding to the end of radiotherapy, AIS and ESS scores decreased

significantly in both groups ( $P < 0.001$ ). Compared with the control group, the intervention group had significantly lower AIS scores ( $P < 0.01$ ) and ESS scores ( $P < 0.05$ ), indicating greater improvement in insomnia severity and daytime sleepiness (table 3).

**Table 3.** AIS and ESS scores before radiotherapy and after three courses of treatment

Treatment stage	Group	AIS (score)	ESS (score)
Before radiotherapy	Control group	9.51 ± 2.90	11.15 ± 1.65
	Intervention group	10.59 ± 2.29	10.89 ± 1.24
	P (between groups)	>0.05	>0.05
End of radiotherapy (3 courses)	Control group	5.32 ± 1.65	6.18 ± 1.50
	Intervention group	4.11 ± 1.50	5.17 ± 1.32
	P (between groups)	<0.01	<0.05

**HAMD and SDS scores**

At baseline, HAMD and SDS scores were comparable between the two groups ( $P > 0.05$ ). After three treatment courses, both groups showed significantly reduced HAMD and SDS scores compared with baseline ( $P < 0.05$ ), indicating an improvement in depressive symptoms. The intervention group had significantly lower HAMD scores ( $P < 0.05$ ) and SDS scores ( $P < 0.01$ ) than the control group at the end of radiotherapy, suggesting that the combined therapy more effectively alleviated radiotherapy-related negative emotions (table 4).

**Table 4.** HAMD and SDS scores before radiotherapy and after three courses of treatment.

Observations	Group	Before radiotherapy	End of radiotherapy (3 courses)	P (within group)
HAMD (score)	Control group	22.40 ± 5.60	16.60 ± 4.91	<0.05
	Intervention group	23.01 ± 5.97	14.21 ± 4.78	<0.05
	P (between groups)	>0.05	<0.05	—
SDS (score)	Control group	54.92 ± 6.23	46.33 ± 6.64	<0.05
	Intervention group	54.46 ± 5.81	41.87 ± 3.89	<0.05
	P (between groups)	>0.05	<0.01	—

**Mattress sleep monitoring system (MSMSMS) scores**

According to the mattress sleep monitoring system, sleep latency and deep sleep percentage were similar between the two groups before radiotherapy ( $P > 0.05$ ). After three treatment courses, both groups showed significantly shorter sleep latency and higher deep sleep percentages compared with baseline ( $P < 0.05$ ). The intervention group had a significantly shorter sleep latency than the control group ( $P < 0.001$ ) and a significantly higher deep sleep percentage ( $P < 0.05$ ) at the end of

radiotherapy, indicating a more favorable improvement in objective sleep structure (table 5).

**Table 5.** Mattress sleep monitoring system results before radiotherapy and after three courses of treatment.

Observations	Group	Before radiotherapy	End of radiotherapy (3 courses)	P (within group)
Sleep latency (min)	Control group	46.58±17.52	38.65±13.87	<0.05
	Intervention group	46.39±17.19	33.01±14.08	<0.05
	P (between groups)	>0.05	<0.001	—
Deep sleep percentage (%)	Control group	14.67±6.12	17.91±4.63	<0.05
	Intervention group	13.79±6.81	18.26±6.04	<0.05
	P (between groups)	>0.05	<0.05	—

**Sleep logs**

Sleep logs showed that before radiotherapy there were no significant differences between the two groups in total sleep time or number of nocturnal awakenings. After three treatment courses, total sleep time increased and the number of awakenings decreased significantly in both groups compared with baseline ( $P < 0.05$ ). The intervention group achieved a significantly longer total sleep time ( $P < 0.01$ ) and fewer awakenings ( $P < 0.05$ ) than the control group at the end of radiotherapy, suggesting a more marked improvement in subjective sleep continuity (table 6).

**Table 6.** Sleep log analysis before radiotherapy and after three courses of treatment.

Observations	Group	Before radiotherapy	End of radiotherapy (3 courses)	P (within group)
Total sleep time (min)	Control group	128.83±44.05	241.60±41.17	<0.05
	Intervention group	129.07±43.96	276.59±42.64	<0.05
	P (between groups)	>0.05	<0.01	—
Awakenings (times/night)	Control group	4.47±1.60	2.96±1.24	<0.05
	Intervention group	4.51±1.67	1.77±1.27	<0.05
	P (between groups)	>0.05	<0.05	—

**TCM syndrome scores**

Before treatment, TCM syndrome scores (e.g., restlessness, palpitations, fatigue, and poor appetite) did not differ significantly between the two groups. After three treatment courses, both groups showed significant improvement in these TCM symptoms ( $P < 0.01$ ), and the intervention group had significantly lower syndrome scores than the control group ( $P < 0.05$ ), indicating that acupuncture and moxibustion combined with the decoction more effectively improved heart and spleen deficiency.

### DBAS scores

Before treatment, dysfunctional beliefs and attitudes about sleep were similar in both groups. After treatment, DBAS scores decreased in both groups, but the intervention group showed significantly lower scores in domains including fear of insomnia consequences, insomnia helplessness, sleep expectation, and beliefs about drug treatment ( $P < 0.001$ ) compared with the control group, indicating a greater improvement in maladaptive sleep-related cognitions (table 7).

**Table 7.** DBAS insomnia helplessness scores before and after treatment.

Observations	Group	Before radiotherapy	End of radiotherapy	P (within group)
Insomnia helplessness (score)	Control group	5.47 ± 0.37	4.60 ± 0.72	<0.05
	Intervention group	5.43 ± 0.40	2.12 ± 0.84	<0.001
	P (between groups)	>0.05	<0.001	—

### Cerebral blood flow

At baseline, there were no significant differences in cerebral blood flow indices between the two groups. After treatment, the intervention group showed significantly higher peak systolic (Vp) and end-diastolic (Vd) velocities in the left middle cerebral artery (LMCA), left vertebral artery (LVA), right vertebral artery (RVA), and basilar artery (BA) than the control group ( $P < 0.01$ ), indicating improved cerebral blood flow. The change in Vp of the LMCA is shown in table 8.

**Table 8.** Cerebral blood flow (Vp of LMCA) before and after treatment.

Observations	Group	Before radiotherapy	End of radiotherapy	P (within group)
Vp (LMCA, cm/s)	Control group	74.842±8.16	84.992±5.953	<0.05
	Intervention group	73.794±7.292	88.65±3.831	<0.01
	P (between groups)	>0.05	<0.01	—

### Therapeutic effect

The total effective rate for insomnia (cured + markedly effective + effective) was significantly higher in the intervention group (94.43%) than in the control group (71.43%) ( $P < 0.05$ ). The intervention group had more cured cases and fewer invalid cases than the control group, indicating superior overall therapeutic efficacy (table 9).

**Table 9.** Therapeutic effect comparison between the two groups.

Curative effect	Control group (n = 35)	Intervention group (n = 35)
Cured	7 (20.00%)	18 (51.43%)
Markedly effective	10 (28.57%)	9 (25.71%)
Effective	8 (22.86%)	6 (17.14%)
Invalid	10 (28.57%)	2 (5.72%)
Total effective rate	71.43%	94.43%

## DISCUSSION

Insomnia in cancer patients undergoing radiotherapy represents a significant clinical challenge, as it exacerbates the physical and psychological burdens associated with cancer treatment. Radiotherapy, while essential for targeting malignant cells, frequently induces side effects such as fatigue, pain, anxiety, and neurovascular changes, all of which contribute to sleep disturbances<sup>(20)</sup>. In the framework of Traditional Chinese Medicine (TCM), insomnia in this population is often attributed to heart and spleen deficiency, characterized by qi and blood imbalances that disrupt yin–yang harmony<sup>(21)</sup>. The present randomized controlled study shows that acupuncture and moxibustion combined with modified Yangxin Anshen Decoction can effectively improve sleep quality, reduce negative emotions, and enhance cerebral blood flow in cancer patients with insomnia undergoing radiotherapy, suggesting a feasible integrative strategy for managing radiotherapy-related sleep disorders.

The mechanisms by which radiotherapy disrupts sleep are multifactorial and involve both direct physiological and indirect psychological pathways. Radiation-induced inflammation and oxidative stress are known to alter neurotransmitter activity, particularly in serotonin and melatonin systems that are critical for sleep–wake regulation<sup>(22)</sup>. In addition, radiotherapy-related pain, fatigue, and treatment anxiety may further aggravate sleep disturbances, especially in patients with underlying heart and spleen deficiency who present with restlessness, palpitations, and reduced appetite<sup>(23,24)</sup>. Our findings that the intervention group had more marked improvements in PSQI domains, AIS scores, and ESS scores than the control group suggest that combining acupuncture and moxibustion with a nourishing and mind-calming decoction can more comprehensively address both the physiological and emotional components of radiotherapy-related insomnia.

The observed improvements are consistent with previous studies reporting that acupuncture and related TCM therapies can significantly improve subjective sleep quality, shorten sleep latency, and enhance daytime function in patients with primary insomnia or insomnia secondary to chronic diseases<sup>(25)</sup>. Similar to those reports, patients in the present study experienced better sleep continuity and reduced daytime sleepiness after treatment. However, most earlier trials focused on non-cancer populations or did not specifically examine patients undergoing radiotherapy. By targeting patients receiving external beam radiotherapy for solid tumors, this study extends existing evidence to a high-risk group with complex, treatment-related sleep disturbances. The greater improvements seen in the intervention group compared with decoction alone suggest that acupuncture and moxibustion provide

an additional therapeutic benefit beyond herbal therapy, likely through modulation of autonomic nervous system balance, enhancement of parasympathetic activity, and reduction of physiological arousal<sup>(26)</sup>.

Emotional disturbances such as anxiety and depression are common in patients receiving radiotherapy and can worsen insomnia and impair treatment adherence<sup>(27)</sup>. In this study, both groups showed reductions in HAMD and SDS scores, but the intervention group exhibited significantly greater improvement. These results are in line with reports that acupuncture can alleviate depressive and anxiety symptoms by influencing monoamine neurotransmitters, hypothalamic–pituitary–adrenal axis activity, and inflammatory markers<sup>(28, 29)</sup>. The additional improvement in Dysfunctional Beliefs and Attitudes about Sleep (DBAS) scores in the intervention group suggests that better sleep and emotional relief may also help patients adopt less catastrophic and more adaptive cognitions about sleep, which is particularly important in radiotherapy settings where fear of treatment outcomes often fuels maladaptive thinking<sup>(30)</sup>.

Objective sleep monitoring and cerebral blood flow assessments provide further support for the effectiveness of the combined intervention. Mattress-based sleep monitoring showed that the intervention group achieved greater reductions in sleep latency, increased deep sleep percentage, and longer total sleep time than the control group, indicating a favorable restructuring of sleep architecture. Previous studies have suggested that acupuncture can enhance slow-wave sleep and normalize sleep–wake cycles, possibly by modulating thalamocortical networks and melatonin secretion<sup>(22, 31)</sup>. In addition, we found that cerebral blood flow indices, such as peak systolic and end-diastolic velocities in the middle cerebral and vertebrobasilar arteries, improved more in the intervention group than in the control group. This finding is consistent with reports that acupuncture at points such as Baihui, Xinchu, and Pishu can improve regional cerebral perfusion and oxygenation<sup>(32, 33)</sup>. Improved cerebral blood flow may help mitigate neurovascular changes induced by radiotherapy and contribute to better cognitive and sleep outcomes.

The tailored use of modified Yangxin Anshen Decoction also appears to have played an important role in symptom relief. The base formula, containing wild jujube kernels, baiziren, Albizia julibrissin, and Schisandra chinensis, is designed to nourish the heart and spleen, calm the mind, and harmonize qi and blood. Symptom-based additions such as Shanzhi for sore throat, Tribulus terrestris and Prunella vulgaris for hypertension, Gorgon seed and dodder for nocturnal polyuria, and calcined corrugated seed for excessive gastric acid allowed individualized adjustment to radiotherapy-related side effects. By

alleviating physical discomforts such as throat pain, nocturia, and dyspepsia, the decoction likely contributed to the reduction in nighttime awakenings and the improvement in overall sleep quality<sup>(34)</sup>. These findings agree with previous TCM clinical reports in which individualized herbal prescriptions improved sleep while also addressing concomitant somatic symptoms in patients with insomnia<sup>(35)</sup>.

Taken together, the present results indicate that integrating acupuncture and moxibustion with a syndrome-targeted TCM decoction can offer several advantages over decoction alone or conventional hypnotic medications for radiotherapy-related insomnia. Compared with sedative–hypnotic drugs, which may cause dependency, tolerance, cognitive impairment, and unfavorable interactions with chemotherapy or radiotherapy<sup>(36)</sup>, the combined TCM-based regimen demonstrated a high total effective rate, favorable safety profile in clinical observation, and potential benefits on emotional status and cerebral hemodynamics. The focus on heart and spleen deficiency as the core TCM pattern provides a coherent theoretical basis for treatment selection and may facilitate broader implementation in integrative oncology practice.

The novelty of this study lies in its specific focus on cancer patients undergoing radiotherapy, the use of a combined acupuncture–moxibustion–herbal approach tailored to heart and spleen deficiency, and the incorporation of both subjective scales and objective measures, including mattress-based sleep monitoring and transcranial Doppler assessment of cerebral blood flow. While previous research has documented the value of acupuncture and TCM formulas in general insomnia populations, few studies have examined radiotherapy patients with clearly defined TCM patterns and have simultaneously evaluated sleep, mood, cognition, and cerebral perfusion. Our findings therefore provide preliminary evidence supporting the integration of TCM-based strategies into supportive care for patients receiving radiotherapy.

This study has several limitations. First, the sample size ( $n = 70$ ) was relatively small, which may limit the generalizability of the findings and the power to detect subgroup differences. Second, we did not stratify patients by specific cancer type, radiotherapy target volume, or technique (e.g., IMRT vs. 3D-CRT), all of which may influence the severity of insomnia and response to treatment. Third, the observation period was limited to the radiotherapy course and three treatment cycles, and we did not conduct long-term follow-up to determine the durability of the benefits after completion of radiotherapy. Fourth, concomitant medications such as analgesics, antiemetics, or psychotropic drugs were not fully controlled, and their potential influence on sleep and mood cannot be completely excluded. Finally, the absence of a sham acupuncture

control group makes it difficult to separate specific acupuncture effects from non-specific placebo or expectancy effects. Future multicenter trials with larger sample sizes, longer follow-up, stratification by cancer type and radiotherapy regimen, and inclusion of sham or minimal acupuncture controls are needed to confirm these results and further clarify mechanisms.

## CONCLUSION

In conclusion, this study suggests that acupuncture and moxibustion combined with modified Yangxin Anshen Decoction can significantly improve sleep quality, reduce depressive symptoms, correct maladaptive sleep-related cognitions, and enhance cerebral blood flow in cancer patients with insomnia of heart and spleen deficiency undergoing radiotherapy. Compared with decoction alone, the combined intervention achieved a higher total effective rate and more pronounced improvements in both subjective and objective indicators, while avoiding the drawbacks associated with long-term use of sedative-hypnotic medications. These findings support the use of an integrative TCM-based approach as a promising, low-risk option for managing radiotherapy-related insomnia and improving quality of life in this vulnerable patient population. Further well-designed, large-scale clinical studies are warranted to validate these results and to explore the long-term impact of such interventions on treatment adherence, functional status, and overall prognosis.

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**Author contributions:** L.D.: Conceptualized the study, designed the methodology, supervised the research, performed acupuncture treatments, and drafted the manuscript. G.L.: Conducted data collection, performed statistical analysis, prepared the Yangxin Anshen Decoction, and contributed to manuscript revision. Both authors reviewed and approved the final manuscript.

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