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Original Article

Moxibustion for medical personnel with negative emotion and insomnia during COVID-19 pandemic: A randomized, controlled trial

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ABSTRACT

Background: We conducted this randomized controlled trial (RCT) to evaluate the effectiveness and safety of moxibustion at Sanyinjiao (SP6) acupoint for treatment of negative mood and sleep quality in healthcare workers during the 2019 coronavirus disease (COVID-19).

Methods: A total of 180 participants were divided in a 1:1 ratio into two groups, the treatment group (for moxibustion) and the control group (for no treatment). The treatment group had a 30-minute moxibustion therapy once a day for two weeks, followed by a two-week follow-up. The Hamilton Anxiety Scale (HAMA) was used to assess the degree of the participants' anxiety, and the Patient Health Questionnaire-9 (PHQ-9) was utilized to examine their depressed condition. The Maslach Burnout Inventory-General Survey (MBI-GS) was used to measure the level of burnout among healthcare workers. To determine the severity of insomnia, the Sleep Dysfunction Rating Scale (SDRS) was utilized. At baseline, week 2, and week 4, all scales were evaluated.

Results: Compared to the control group, The treatment group improved more significantly in the HAMA at week 2 (MD = -19.01, 95% CI: -21.89 to -16.14; $P<0.001$) and at week 4 follow-up visits (MD = -8.96, 95% CI: -11.19 to -6.73; $P<0.001$). A subgroup study of HAMA scores revealed that position and education had significant impact on treatment effectiveness. During the 2-week intervention period, the treatment group showed more significant improvements in depressive symptoms measured by PHQ-9 (13.00±2.41 vs. 15.60±3.65; $P<0.001$), work burnout symptoms measured by MBI-GS (MD = -11.88, 95% CI, -15.73 to -8.03; $P<0.001$), and insomnia symptoms measured by SDRS (MD = -2.45, 95% CI, -4.24 to -0.66; $P<0.01$). There were no significant adverse effects reported.

Conclusion: Moxibustion at SP6 may be an effective treatment to improve anxiety, depression, sleep quality, and quality of life for healthcare workers during COVID-19.

Trial registration: Chinese Clinical Trial Registry (ChiCTR): ChiCTR-2200059327.

1. Introduction

Coronavirus disease 2019 (COVID-19) was first identified in late 2019 in Wuhan, China, and quickly spread throughout the country. Following outbreaks of the disease in Asia, Europe, North America, and Oceania, the disease developed into a global pandemic.[1] So far, the virus has evolved multiple times, with Omicron being the most common pandemic strain.[2] The Omicron virus was widely transmitted in Shanghai, China, in late February 2022.[3,4] According to data given by the Shanghai Municipal Health Commission, there were 593,336 confirmed cases of COVID-19 infection as of 4 May 2022.[3] Over 763 million confirmed cases of COVID-19 infection and over 6.9 million deaths had been documented worldwide as of April 16, 2023.[5] China has stopped the spread of several outbreaks by lockdown measures, proactive case monitoring, rapid case diagnosis, and successful contact tracing.[6,7] Furthermore, the construction of makeshift hospitals offered an efficient medical setting for the growing number of confirmed cases. Therefore, a large number of medical personnel were required to provide medical services in these hospitals, which played an indispensable role in this public health emergency.

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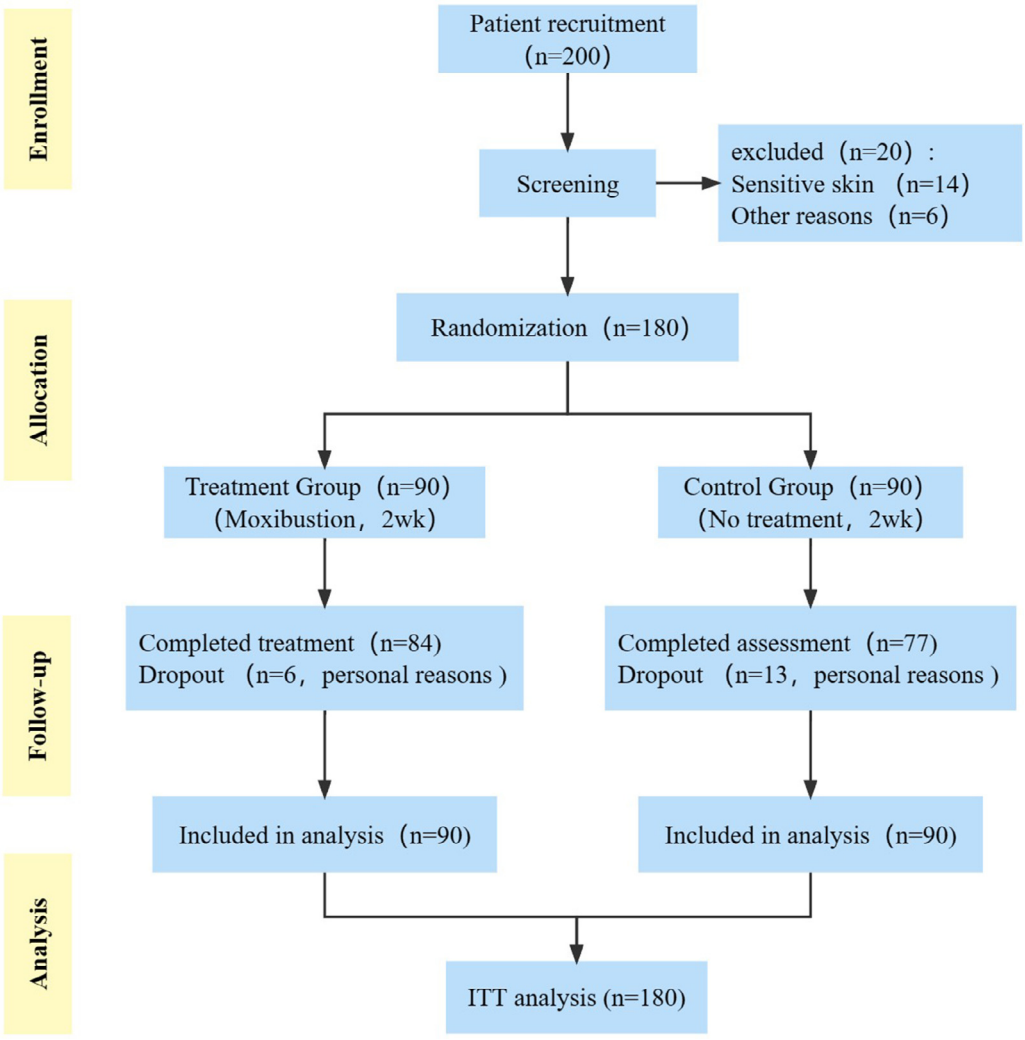


Fig. 1. Study flow diagram.

During the outbreak, medical staff were subjected to heavy workloads and multiple life-threatening stresses, which resulted in mental health issues such as anxiety, depression, insomnia and suicidal thoughts.[8-10] A recent systematic review and meta-analysis suggested that the prevalence of anxiety among healthcare workers during the pandemic was 23.2%, depression was 22.8%, and insomnia was an estimated 38.9%.[11] Therefore, there is an urgent need for methods to reduce mental health risks and improve intervention implementation in pandemic conditions.

Moxibustion is effective in treating mental health issues such as anxiety, depression, and insomnia.[12-14] Moxibustion is reported to regulate the hypothalamic-pituitary-adrenal (HPA) axis, hippocampus upregulation, and neurotransmitter synthesis for depression relief.[15] Moxibustion has been shown in studies to improve the sleep state of insomnia rats by increasing 5-hydroxytryptamine (5-HT) and 5-hydroxyindoleacetic acid levels in the hypothalamus while decreasing dopamine and norepinephrine levels.[16] Another study showed that moxibustion can improve anxiety behavior in colitis rats and the effect may be partly due to the increase in HPA axis balance.[13] However, randomized controlled trials (RCTs) on whether moxibustion of a single acupoint can relieve anxiety, depression, and insomnia are lacking. Therefore, we conducted this RCT to evaluate the effectiveness of moxibustion at SP6 on the negative mood and sleep quality of medical professionals fighting COVID-19, as well as keep track of adverse responses during therapy.

2. Methods

2.1. Participants

Participants in this study included medical workers from Shanghai's Changxing Island's square cabin hospital. The study took place between April and June of 2022. Participants were screened over the phone or in person, and eligible participants were required to sign a written informed consent form prior to the beginning intervention. The Shanghai Municipal Hospital of TCM's Ethics Committee (2022SHL-KY-22–02) approved of the protocol.

2.1.1. Inclusion criteria

This study's inclusion criteria were as follows: (1) medical staff at Changxing Island's square cabin hospital; (2) age 18 to 60 years old, male or female; and (3) agree to participate in the study and sign a written informed consent form.

2.1.2. Exclusion criteria

Participants were banned from participating if they: (1) had a history of mental health issues or previous psychiatric disorders; (2) had severe cardiac, brain, hepatic, and renal impairment, congestive lung disease, or other severe systemic disease; (3) had severe ulcers, abscesses, skin

Table 1
Baseline characteristics of participants.

Characteristic	Moxibustion (n = 90)	No treatment (n = 90)	P
Gender, n (%)			1.000
Male	17 (18.9%)	16 (17.8%)	
Female	73 (81.1%)	74 (82.2%)	
Age, Median (IRQ)	33.5 (29, 40)	33 (27, 36)	0.122
Occupation, n (%)			0.186
Doctor	30 (33.3%)	21 (23.3%)	
Nurse	60 (66.7%)	69 (76.7%)	
Education, n (%)			0.022
Graduate and above	28 (31.1%)	14 (15.6%)	
College or Below university	62 (68.9%)	76 (84.4%)	
Marriage, n (%)			0.383
Unmarried	31 (34.4%)	39 (43.3%)	
Married	56 (62.2%)	47 (52.2%)	
Divorced/widowed	3 (3.4%)	4 (4.5%)	
Annual income, n (%)			0.501
> 200,000/year	15 (16.7%)	12 (13.3%)	
100,000–200,000/year	57 (63.3%)	58 (64.4%)	
50,000–100,000/year	18 (20.0%)	20 (22.3%)	
Current smokers, n (%)			0.211
Yes	5 (5.6%)	1 (1.1%)	
No	85 (94.4%)	89 (98.9%)	
Drinkers, n (%)			1.000
Yes	2 (2.2%)	3 (3.3%)	
No	88 (97.8%)	87 (96.7%)	
Daily exercise, n (%)			0.576
Yes	20 (22.2%)	16 (17.8%)	
No	70 (77.8%)	74 (82.2%)	
Participated in the fight against the COVID-19 before, n (%)			0.096
Yes	59 (65.6%)	47 (52.2%)	
No	31 (34.4%)	43 (47.8%)	
HAMA, Mean±SD	26.89±10.93	28.20±5.98	0.320
PHQ-9, Mean±SD	14.96±6.17	15.44±5.41	0.573
MBI-GS, Mean±SD	53.64±11.54	51.76±12.55	0.295
SDRS, Mean±SD	26.73±8.33	26.71±6.60	0.984

HAMA, Hamilton Anxiety Scale; MBI-GS, Maslach Burnout Inventory – General Survey; PHQ-9, Patient Health Questionnaire-9; SD, standard deviation; SDRS, Sleep Dysfunction Rating Scale.

infections, etc. at the site of moxibustion; (4) were pregnant or breast-feeding women; (5) had participated in other clinical medical studies.

2.1.3. Sample size calculation

The calculation of the sample size was based on the change in HAMA scores. Based on previous research,[17] we assume that the difference between the treatment group and the control group was 4 points, with a standard deviation of 7.2, and a sample size of 70 per group, a 90% confidence level with a significance level of 0.05 was a two-tailed, two-sample, unequal-variance t-test. Given the 20% dropout rate, a sample size of 90 cases was required for a single group.

2.2. Randomization

A simple randomization method was used in this study. An independent statistician generated the randomization sequence using SPSS 26.0. Participants who met the criteria were randomly assigned to one of the two groups in a 1:1 ratio. Randomization was obscured by opaque envelopes that were provided in duplicate to the study sponsor and research center. To minimize observer bias, the principal investigator who designed the study and the research staff conducting outcome assessments were blinded to group assignment.

2.3. Interventions

Patients in the treatment group received 30 min of moxibustion treatment at SP6 (Supplement 1A) once a day for 14 days.[18] The researcher sent them an instructional video with instructions on how to perform the moxibustion treatment. The moxa cone was 3 cm long, 1.5 cm in diameter and weighed about 15 g. The lighted moxa cone was taped to the specific device, with a tight tape sticking to the local skin around the acupuncture point to prevent the moxibustion device from falling (Supplement 1B, C). In order to prevent accidents, participants were urged not to sleep during the treatment. In the event of scalding, a thin layer of cotton wool can be placed between the moxa cone and the skin. Follow-up was two weeks after the end of treatment. Control group participants were asked to complete a questionnaire at the end of the two-week and follow-up periods, with no moxibustion treatment administered during the study.

2.4. Outcome measures

We assessed all indicators in patients in both groups at day 0 (baseline), week 2 (end of treatment) and week 4 (follow-up period).

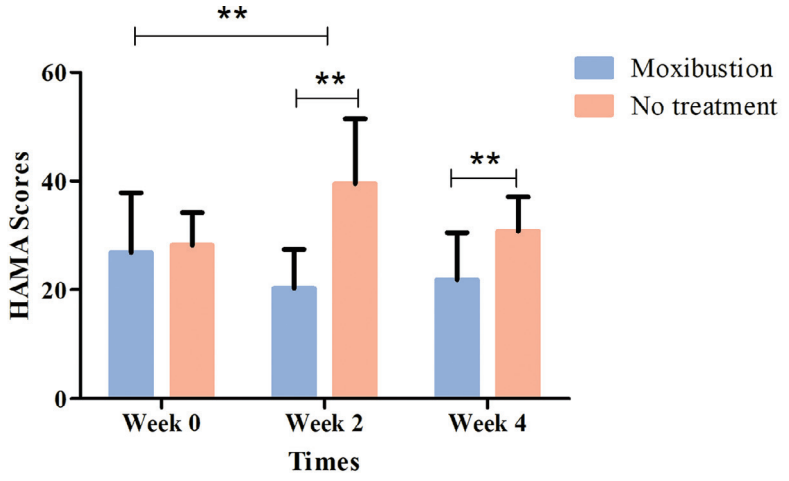
2.4.1. Primary outcome

2.4.1.1. Hamilton anxiety scale (HAMA). HAMA was assessed as the primary outcome 2 weeks after treatment. HAMA was introduced as a rating scale for anxiety neurosis severity.[19]

2.4.2. Secondary outcomes

2.4.2.1. Patient health questionnaire-9 (PHQ-9). PHQ-9 is based on the major depressive disorder diagnostic criteria and is an important tool recommended by the World Health Organization (WHO) in recent years for the screening and assessment of depression and anxiety, with the characteristics of easy operation and high specificity.[20,21]

2.4.2.2. Maslach burnout inventory – general survey (MBI-GS). The 15-item MBI-GS is currently widely used to measure workplace burnout among healthcare workers.[22] The higher the total score, the higher the burnout level.



Characteristics	N (%)	HAMA	Difference Between Groups (95% CI)	P
Gender	180		-4.40(-10.24~1.43)	0.138
Male	33 (18.3%)	26.10± 2.74		
Female	147 (81.7%)	30.51± 1.09		
Position	180		-5.80(-10.25~-1.35)	0.011
Doctor	51 (28.3%)	25.74± 1.90		
Nurse	129 (71.7%)	31.54± 1.19		
Education	180		-6.47(-11.25~-1.70)	0.008
Graduate and above	42(23.3%)	24.93± 2.11		
College or Below university	138(76.7%)	31.41± 1.15		
Current smokers	180		-1.21(-12.42~10.00)	0.832
Yes	6(3.3%)	28.73± 5.59		
No	174(96.7%)	29.94± 1.04		
Drinkers	180		4.91(-7.29~17.12)	0.428
Yes	5(2.8%)	34.67± 6.10		
No	175(97.2%)	29.76± 1.03		
Exercise daily	180		-0.6(-5.62~4.42)	0.814
Yes	36(20.0%)	29.42± 2.28		
No	144(80.0%)	30.01± 1.14		
Participated in the fight against the COVID-19 before	180		-3.54(-7.58~0.51)	0.086
Yes	106 (58.9%)	28.44± 1.32		
No	74 (41.1%)	31.98± 1.57		

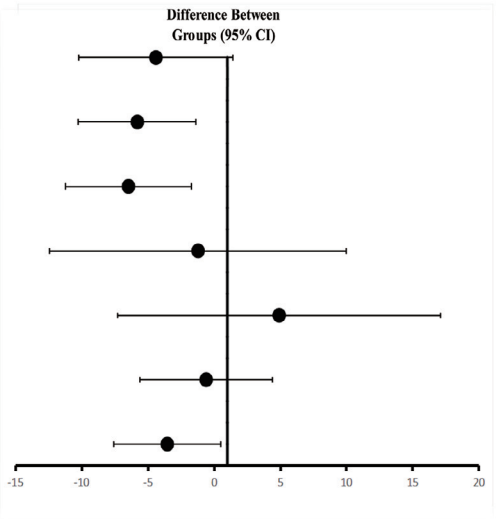


Fig. 2. Effects of moxibustion on HAMA score. (A) Means change from baseline to follow-up in HAMA score. (B) Treatment effect on HAMA score by subgroup analysis.

2.4.2.3. Sleep dysfunction rating scale (SDRS). The SDRS is a short scale that can rapidly assess insomnia based on the Chinese Classification and Diagnostic Criteria for Mental Disorders Version 3 (CCMD-3) and is a quantitative assessment tool for the severity of insomnia with strong reliability and validity. The higher the total score, the more severe the sleep disorder.[23]

2.5. Statistical analysis

SPSS 26.0 statistical analysis software for Windows was used to analyze the data. Two researchers entered the data twice to ensure integrity and accuracy. Analysis of covariance (ANCOVA) was used to compare other measures between groups from baseline to follow-up and for subgroup analysis. The two measurement data sets were compared with the *t*-test, the grade data were tested with the rank sum test; and the count data was analyzed with χ^2. The level of significance for statistical analysis using a two-tailed test was 5%. Data values were presented primarily as Mean±SD. The missing data were calculated using the Last Observation Carry Forward (LOCF) method.

3. Results

3.1. Participants' characteristics

We examined a total of 200 eligible participants, 20 of whom were excluded for various reasons. Of those, 14 were excluded due to sensitive skin and 6 due to other reasons (Fig. 1). The remaining 180 participants were randomly assigned to the treatment group and the control group. A total of 19 participants dropped out of the study due to personal problems.

The baseline characteristics of all participants are presented in Table 1. There were significant statistical differences in educational attainment and position between the two groups ($P<0.05$). There were no significant differences in clinical characteristics and other demographic characteristics between the two groups (all $P>0.05$).

3.2. Assessment of anxiety

After two weeks of treatment, the HAMA score of the treatment group was significantly lower than that of the control group (MD = −19.01 [95% CI, −21.89 to −16.14]; $P<0.001$). Similar results were found at week 4, and there was a statistically significant difference in HAMA scores between the two groups (MD = −8.96 [95% CI, −11.19 to −6.73]; $P<0.001$). (Fig. 2A, Supplement 2).

A subgroup analysis of HAMA scores was performed before and after treatment (Fig. 2B). Treatment outcomes were not influenced by gender, smoking, alcohol consumption, exercise routines, or whether they had previously participated as medical volunteers for COVID-19 (all $P>0.05$). However, occupation and education of medical staff had a significant impact on treatment effectiveness ($P<0.05$).

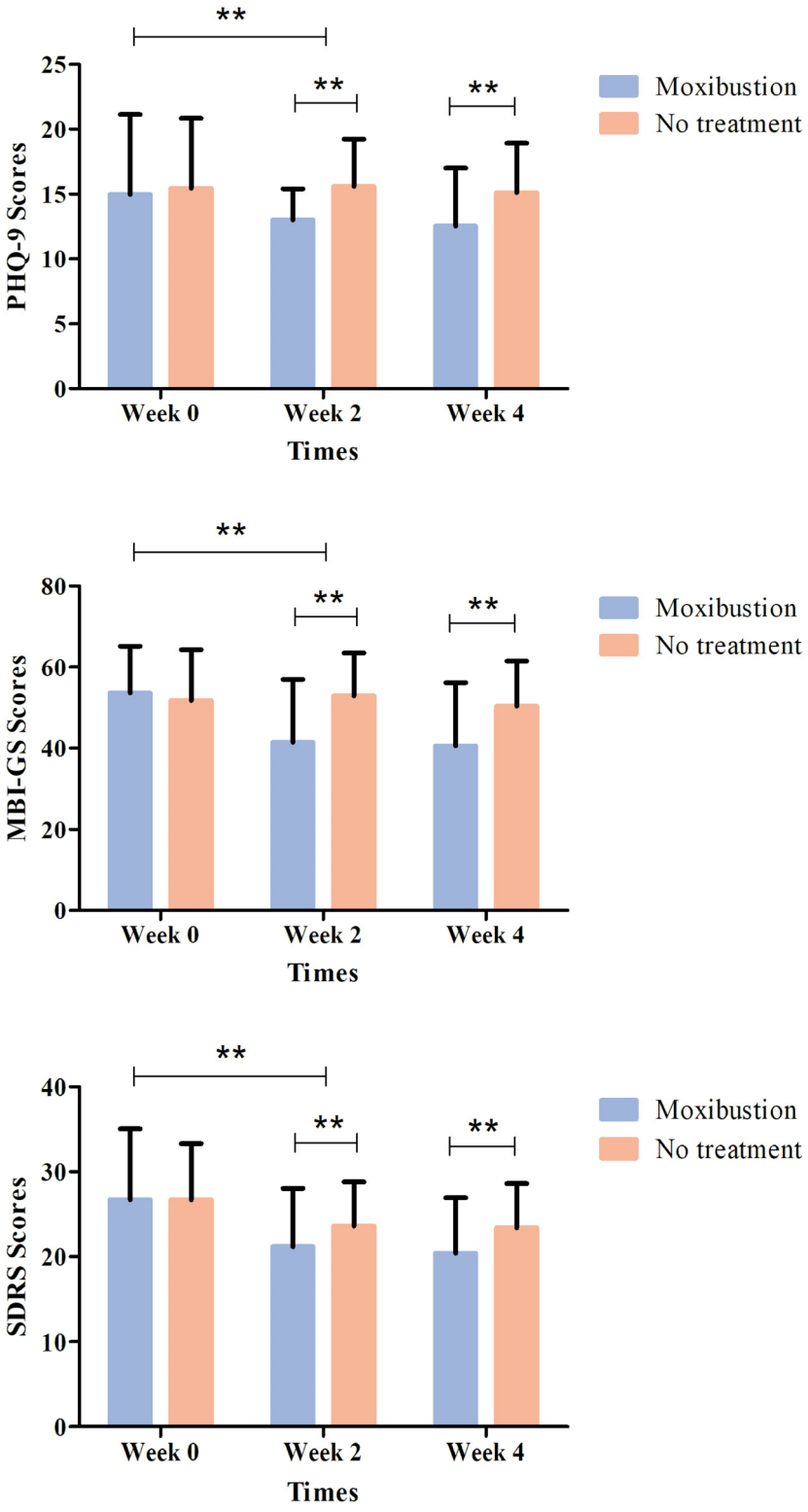


Fig. 3. Means change from baseline to follow-up in secondary outcomes. (A) Means change from baseline to follow-up in PHQ-9 scores. (B) Means change from baseline to follow-up in MBI-GS scores. (C) Means change from baseline to follow-up in SDRS scores.

3.3. Evaluation of depression screening

After two weeks of treatment, the PHQ-9 score of the treatment group was significantly higher than that of the control group (MD = −2.53 [95% CI, −3.41 to −1.65]; $P<0.001$). Follow-up results two weeks after treatment showed that the PHQ-9 score of the treatment group was significantly higher than that of the control group (MD = −2.57 [95% CI, −3.80 to −1.35]; $P<0.001$) (Fig. 3A, Supplement 2).

3.4. Assessment of occupational burnout

There is a baseline imbalance in professional efficacy, but this does not affect the baseline level of the total MBI-GS score. After two weeks of treatment, the MBI-GS of the emotional exhaustion, cynicism, and occupational efficacy treatment groups were significantly reduced compared to the control group (all $P<0.01$) (Fig. 3B, Supplement 2). At week 4 follow-up, emotional exhaustion and occupational efficacy scores decreased significantly in the treatment group compared to the control

group (P<0.001, respectively). After 2 weeks of treatment, there was a statistically significant difference between the MBI-GS scores of the treatment group and the control group (MD = −11.88 [95% CI, −15.73 to −8.03]; P<0.001). At week 4, there was a statistically significant difference in MBI-GS scores between the two groups (MD = −9.88 [95% CI, −13.88 to −5.88]; P<0.001).

3.5. Sleep disorder assessment

From baseline to the end of follow-up, treatment group SDRS scores continued to decrease (Fig. 3C, Supplement 2). Compared to the control group, the SDRS score of the treatment group was significantly lower after 2 weeks of treatment (MD = −2.45 [95% CI, −4.24 to −0.66]; P<0.01), and moxibustion's effectiveness in treating insomnia maintained during the follow-up period (20.42±6.53 vs 23.43±5.18; MD = −3.01 [95% CI, −4.75 to −1.27]; P<0.01), with statistically significant differences.

3.6. Infection rate during the trial process

During the trial, we found that the infection rate was 5.6% in the control group about five participants were infected, but none in the treatment group. There was no difference in infection rate between groups (P>0.05, Supplement 3).

4. Discussion

Our study used moxibustion therapy for two weeks on SP6 and found that it significantly decreased the HAMA, PHQ-9, MBI-GS, and SDRS levels of medical staff working in square cubicle hospitals in Shanghai during the outbreak of COVID-19. The results demonstrated that moxibustion treatment could effectively mitigate their anxiety, depression, and burnout, as well as enhance their sleep quality. This therapeutic effect was present during the two-week treatment phase and persisted during the two-week follow-up period. During the study, no serious adverse events were reported, implying that moxibustion may be a safe treatment to improve anxiety, depression, quality of life, and sleep quality in healthcare workers during the COVID-19 epidemic.

Regarding baseline characteristics, there were statistically significant differences in educational level between the two groups. However, as the outcome of the subgroup analysis, the educational level and position have an effect on the HAMA scores after treatment. We guessed that nurses undertake more work in close contact with patients and face more risks than doctors based on job duties. The different levels of education of the subjects mean that the learning time and level of professional knowledge are different, and there may be other influencing factors that deserve further exploration.

Some studies suggest that moxibustion in combination with other therapies is safe and effective in improving anxiety, depression, quality of life, and sleep quality. One RCT showed that electro-acupuncture combined with moxibustion has shown efficacy and safety in the treatment of major depressive disorder, such as it can significantly reducing patients' depression scores.[14] The results of a systematic review and meta-analysis show that Warm needle acupuncture has significant efficacy and high safety in improving sleep quality of and quality of life in patients and reducing the severity of insomnia.[24] Another systematic review and meta-analysis found that auricular compressions combined with moxibustion lowered sleep quality, depression.[25] Another systematic review and meta-analysis also found that moxibustion was more effective in treating insomnia than western medicine, and the incidence of adverse events is lower.[26] But our research suggests that moxibustion of a single acupoint has such an effect and no serious adverse events were reported.

It has also been shown that moxibustion can enhance the body's immunity by modulating various immune cells and immune factors.[27,28] During the treatment of Severe Acute Respiratory Syndrome-Cov (SARS-Cov), which has a similarity rate of 79.5% with the gene sequence of COVID-19,[29] patients in the recovery phase of SARS received moxibustion treatment and their symptoms were well alleviated. Peripheral blood CD4+ levels increased, suggesting that moxibustion may improve some of the immune function of SARS patients.[30] In addition, 42 patients were treated with moxibustion throughout the COVID-19 infection phase, and their negative emotions were alleviated.[31] Moxibustion could substantially increase human immunity, reduce the risk of infectious diseases, and diminish the elements that influence negative emotions.

The SP6 is always recommended by the evidence-based guidelines of TCM as the main acupuncture point for the treatment of insomnia.[32] A systematic review included 4 studies with 288 participants and showed that SP6 stimulation improved sleep quality, prolonged deep sleep time and prolonged rapid eye movement (REM) duration.[12] Research also showed that stimulation at SP6 improved sleep quality by increasing levels of 5-HT in the hippocampus in the rat model of insomnia.[16]

The study was designed through a rigorous process with trained medical staff involved in the study in strict adherence to standard operating procedures. Participants were also followed up on to determine the long-term efficacy of moxibustion therapy. This study, however, had several limitations. First, the operating environments were restricted making blinded or pseudo-control groups impossible to include. Second, the study's treatment length was only 14 days, which was relatively short for an intervention. Furthermore, the assessment methodology was insufficiently comprehensive, and objective assessment indicators for biomolecular science were lacking. More large-sample-size studies and longitudinal assessments of study populations are required to provide more scientific evidence.

In conclusion, the results of our study imply that moxibustion at SP6 may be an effective and safe treatment for improving anxiety, depression, quality of life, and sleep quality in healthcare professionals during the COVID-19 outbreak.

CRediT authorship contribution statement

Xiying Li: Software, Formal analysis, Writing – original draft, Visualization. **Xiaojuan Li:** Writing – original draft, Writing – review & editing. **Xian Wang:** Investigation, Project administration. **Xuan Yin:** Methodology, Writing – review & editing. **Shanshan Li:** Investigation. **Junyi Wu:** Investigation. **Xiumei Ren:** Investigation. **Wei Zhang:** Validation, Formal analysis, Visualization, Supervision. **Yiqun Mi:** Conceptualization, Methodology, Resources, Funding acquisition, Supervision. **Shifen Xu:** Conceptualization, Methodology, Resources, Project administration, Funding acquisition.

Conflicts of interest

The authors report no conflicts of interest in this work.

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Ethical statement

The protocol was approved by the Ethics Committee of Shanghai Municipal Hospital of TCM (2022SHL-KY-22–02).

Data Availability

The data supporting these study findings are available upon reasonable request from the corresponding author (Shifen Xu). In addition,

the individual anonymous participant data are available after contacting the relevant author via email (xu_teacher2006@126.com). The data is available immediately after publication with no end date.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.imr.2023.100974.

Supplement 1. Location of SP6 and moxibustion device diagram.

Supplement 2. Changes from Baseline of HAMA, PHQ-9, MBI-GSand SDRS Outcomes at the End of Treatment (2-Week) and Follow-Up Visits (4-Week) by Group.

Supplement 3. Infection rate during the trial process.

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