



Efficacy of simplified-cognitive behavioral therapy for insomnia(S-CBTI) among female COVID-19 patients with insomnia symptom in Wuhan mobile cabin hospital

Jin He¹ · Lei Yang¹ · Jianyue Pang¹ · Lingling Dai² · Jiaojiao Zhu³ · Yajie Deng¹ · Yi He¹ · Hengfen Li¹ 

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Abstract

Background The outbreak of Coronavirus Disease-2019 (COVID-19) caused great psychological distress often with comorbid insomnia. Insomnia is common in patients with COVID-19 admitted to mobile cabin hospitals. Insomnia may lead to immune dysfunction, a condition not conducive to recovery from COVID-19. The use of sedative-hypnotic drugs is limited by their inhibitory effect on the respiratory system. A paucity of research is available regarding psychotherapy interventions to improve insomnia symptoms among patients with COVID-19. In the general population, sleep problems are more common in women than in men; insomnia in women patients requires special attention.

The aim of this study was to develop simplified-cognitive behavioral therapy for insomnia (S-CBTI) for patients with COVID-19 and comorbid insomnia symptoms and to verify its effectiveness through a self-control trial. A second aim was to compare the effectiveness of S-CBTI between acute and chronic insomnia among women with COVID-19 and comorbid insomnia symptoms in Wuhan Jiangnan Cabin Hospital.

Methods S-CBTI consisted of education on COVID-19 and sleep hygiene, stimulus control, sleep restriction, and self-suggestion relaxation training over a period of two consecutive weeks. Of 67 women, 66 completed psychological intervention and baseline and post-intervention assessments. There were 31 women with acute insomnia and 35 with chronic insomnia. The Insomnia Severity Index (ISI) score and self-compiled sleep data were assessed at baseline and post-intervention, and subjective sleep evaluations were assessed at days 4, 7, 12, and 14.

Results The ISI score, sleep latency, night sleep time, and sleep efficiency were statistically significantly improved from baseline to post-intervention by paired *T*-test. After the intervention, the mean ISI score of the acute insomnia group was lower than that of the chronic insomnia group. The reduction of the ISI score and the improvement of sleep time from baseline to post-intervention in the acute insomnia group were greater than those in the chronic insomnia group. Utilization of sedative-hypnotic drugs in the acute insomnia group was less than that in the chronic insomnia group, and the difference was statistically significant.

Conclusions S-CBTI can improve the insomnia symptoms of women with COVID-19 in mobile cabin hospitals, especially for stress-related acute insomnia.

Keywords Simplified-cognitive behavioral therapy for insomnia (S-CBTI) · COVID-19 · Female · Acute insomnia · Chronic insomnia

Jin He and Lei Yang contributed equally to this work.

✉ Hengfen Li
fcclihf2@zzu.edu.com

¹ Department of Psychiatry, Zhengzhou University First Affiliated Hospital, Zhengzhou 450052, Henan, People's Republic of China

² Department of Respiratory, Zhengzhou University First Affiliated Hospital, Zhengzhou 450052, Henan, China

³ Department of Infectious Diseases, Zhengzhou University First Affiliated Hospital, Zhengzhou 450052, Henan, China

Introduction

Coronavirus Disease-2019 (COVID-19) is a highly infectious disease that quickly spread across the world and causing wide-spread concern [1]. In Wuhan, China, patients with mild symptoms were admitted to the mobile cabin hospitals which were constructed in stadiums and conference centers [2]. After being admitted to the mobile cabin hospital, the change in the sleeping environment, the reduction of activity, and the relative isolation from the outside world led to a series of physiological and

psychological stress reactions among patients [3, 4]. Some patients developed acute insomnia related to environment and stress, while other patients' chronic insomnia persisted or was aggravated. Preliminary cross-sectional studies reported the female gender as a risk factor for developing psychological symptoms during the pandemic [5–7]. Female sex has been independently associated with more severe worsening of sleep quality during the pandemic [8]. Insomnia in women requires special attention.

Insomnia may lead to immune dysfunction [9] by contributing to the dysregulation of inflammatory and antiviral responses [10]. This immune dysfunction is not conducive to the recovery from COVID-19. Sedative-hypnotic drugs, including benzodiazepines and the non-benzodiazepine “Z” drugs, are the most commonly prescribed pharmacological treatments for insomnia [11]. However, sedative-hypnotics are associated with central respiratory depression [12]. Prescribing information for hypnotic agents often advises caution in patients with compromised respiratory function. It is an important safety consideration when sedative drugs are used in patients with COVID-19.

Psychological intervention methods for COVID-19 insomnia patients in the mobile cabin hospital have potential advantages. Cognitive-behavioral therapy for insomnia (CBTI) is recommended as a first-line treatment for insomnia by the British Psychopharmacology Association, the European Sleep Research Society, and the American College of Physicians [13–15]. While the effectiveness of CBTI is undeniable, a more concise and effective treatment for insomnia would be useful for major public health events. Previous studies have produced concise versions of CBTI, which have been shown to be effective for insomnia sufferers [16–18]. Recent evidence suggests that CBTI can also be used to treat acute insomnia due to stress [19, 20]. Traditionally, group or individual CBTI is implemented by trained psychiatrists or psychotherapists. It has a set of standardized procedures with complicated steps and a long treatment time. As a result, CBTI can hardly be completed in the setting of public health emergencies, when medical resources are scarce. Therefore, it is very important to find a simple and effective psychotherapy. Several research groups have created briefer versions of CBTI. A brief behavioral treatment for insomnia which has fewer sessions (4), shorter duration (<30–45 min), and delivers in-person treatment plus phone calls was inconclusively non-inferior to CBTI [21]. Digital CBTI was shown to be an effective, scalable, safe, and acceptable intervention for improving insomnia symptoms during pregnancy [22]. Through the provision of self-management, CBTI tools increase the use of CBTI [23]. However, no studies have been conducted in patients with COVID-19 and comorbid insomnia symptoms.

Using the principles of CBTI, we developed a simplified-cognitive behavioral therapy for insomnia (S-CBTI) for women with COVID-19 in cabin hospitals. This study aimed to

verify the effectiveness of S-CBTI through a self-controlled trial in Wuhan Jiangnan Cabin Hospital, and to compare its effect on acute and chronic insomnia. First, we hypothesized that subjective sleep-related indicators would be improved after intervention in patients receiving S-CBTI, including ISI score, sleep latency, sleep time, and sleep efficiency. Second, we hypothesized that S-CBTI would have greater effects on stress-related acute insomnia than on chronic insomnia.

Method

Participants

From February 6 to March 9, 2020, women with COVID-19 and comorbid insomnia symptoms in Wuhan Jiangnan Cabin Hospital were enrolled. Inclusion criteria were as follows: (1) a total score of 8 or greater on the ISI; (2) women, 18–60 years old; (3) cultural and educational background and audiovisual ability sufficient to understand informed consent and research content; (4) patients with a confirmed diagnosis of COVID-19 (mild type or common type) based on “The novel coronavirus pneumonia diagnosis and treatment plan (5th trial version)” in China. Exclusion criteria were: self-reported history of bipolar disorder, borderline personality disorder, antisocial personality disorder, schizophrenia, organic mental disorders, and other psychiatric disorders.

The diagnostic criteria and clinical symptoms of the mild type and common type of COVID-19 were: (1) patients with a positive nucleic acid test for COVID-19 were considered to have COVID-19; (2) patients with mild symptoms (fever and/or cough) and with no pneumonia evident from imaging examination were considered to have mild-type COVID-19; (3) patients with fever and respiratory tract symptoms, along with pneumonia evident from imaging examination, were considered to have common-type COVID-19. Clinical symptoms were mild cough, mild chest tightness, body temperature below 38°C, oxygen saturation > 93%, and respiratory rate <30 times/min.

After patients were admitted to the cabin hospital, sleep status was investigated on the third day. Of the 215 women assessed for eligibility combining a self-report questionnaire and physical examination results, 102 did not meet the eligibility criteria. Among the 46 women who declined to participate, the most common reason was non-completion of the study consent form. A total of 67 patients with insomnia were enrolled. One patient dropped out after the first day because she preferred to rely on sedative-hypnotic drugs to improve sleep. Psychological intervention for eligible insomnia patients was subsequently conducted and 66 patients completed psychological intervention along with baseline and post-intervention evaluations. Patients with insomnia were divided

into an acute insomnia group ($n=31$) and a chronic insomnia group ($n=35$) according to whether or not they often had sleep problems previously (≥ 3 times/week, ≥ 3 months).

Measurement tools

The measurement tools in this study included (1) self-completed general information questionnaire for age, education level, and marital status; (2) brief sleep diary, including bed time, time to fall asleep, wake time, and subjective sleep time; (3) subjective sleep evaluation, including the satisfaction with sleep and the impact of insomnia on daytime function. (4) The Insomnia Severity Index (ISI) was used to measure the severity of insomnia. The ISI has been shown to have good reliability and validity [24] and has been proven to be a clinically useful evaluation tool in insomnia treatment studies [25]. A total score of ≥ 8 was considered as having symptoms of insomnia.

Interventions

The S-CBTI was based on CBT-I manuals, and included 4 main components delivered over 2 weeks: sleep hygiene and education, sleep restriction, stimulus control, and relaxation techniques. There were three phases. (1) Phase 1 (days 1–4): information on COVID-19-related knowledge that all patients admitted to the cabin hospital had mild disease, that all treatment in the cabin was free of charge, introduction of steps for self-protection related to COVID-19, and education on the principles of sleep hygiene. (2) Phase 2 (days 5–12): patients were asked to participate in behavioral therapy by mobile phone-based and paper-based systems, including stimulus control, sleep restriction, and relaxation training through self-suggestion. Relaxation training was comprised of imagining a relaxing scene or recalling a familiar bedroom environment in the past, and applying multiple senses to feel the scene. Patients were asked to repeat the relaxation training every night for 20–30 min. (3) Phase 3 (days 13–14): sessions dealt with group separation, building support systems, and discussing future management of the illness.

A psychiatrist was involved in the procedure of implementation and evaluation. Distribution and recovery of advertising materials and questionnaire surveys were completed by two doctors and one nurse. Since all patients were diagnosed with mild COVID-19 disease, hypnotic drugs were generally not used, but exceptions included: (1) history of long-term sedative-hypnotic drug use or (2) people who had serious sleep problems for 3 days after the start of the intervention. The main drugs were eszolam and alprazolam, followed by the continuation of the previous drug.

Subjective sleep outcomes

The primary outcome for the study was the total score of the ISI. Total scores of 7 or less indicate no clinically significant insomnia, 8 to 14 indicate mild insomnia, 15 to 21 indicate moderate insomnia, and 22 or greater indicate severe insomnia. Sleep diaries were used to measure sleep latency, night sleep duration, and sleep efficiency. Sleep latency is the time from going to bed to falling asleep. Sleep duration was defined as the total amount of nightly sleep in hours. Sleep efficiency was calculated by dividing the amount of time sleeping in bed by the total amount of time spent in bed and multiplying the quotient by 100. Scores ranged from 0 to 100%, with 85% or higher considered normal. The subjective sleep improvement rate was calculated at days 4, 7, 12, and 14. Patients were assessed whether there was an improvement in subjective sleep status compared with baseline or not. The number of patients evaluated for yes was divided by the sum.

Statistical analysis

We compared baseline characteristics between groups using an independent sample t test for continuous variables and χ^2 tests for categorical variables. Paired t -tests were used to determine significant differences between baseline and post-intervention for ISI, sleep latency, night sleep duration, and sleep efficiency. Independent sample T test was used to compare the difference in the improvement of sleep-related indicators between acute and chronic insomnia groups. The use rate of sedative and hypnotic drugs was compared between the two groups by χ^2 test. Statistically significant tests were two-sided. A p -value of <0.05 was considered statistically significant.

Results

Demographic and clinical characteristics at baseline

The enrolled patients were all diagnosed with mild COVID-19, all of whom were women without other serious physical diseases. There were seven patients with chronic diseases such as hypertension or diabetes, including 4 in the acute insomnia group and 3 in the chronic insomnia group. In the acute insomnia group, the hospital stay was 18–26 days, while the chronic insomnia group was 18–28 days. There were no cases transferred to a designated hospital in this study due to worsening of the COVID-19 condition.

The age range of the acute insomnia group (AI) was 19–58 years old, with an average age of 47.3 ± 12.8 years, while that of the chronic insomnia group (CI) was 18–60 years old, with an average age of 52.2 ± 9.2 years. There were no statistically significant differences in age, educational level, marital status,

Table 1 Comparisons between Acute Insomnia (AI) and Chronic Insomnia (CI) participants' baseline demographic and clinical characteristics

	AI (n=31)	CI (n=35)	t/χ^2	p
Age(years)	47.3 (12.8)	52.2 (9.2)	-1.786	0.080
Educational level				
Primary school or below	6	8	0.118	0.943
High school	10	12		
Bachelor or above	14	15		
Marital status			2.173	0.337
Single	5	2		
Married	22	30		
Widow or divorced	2	3		
COVID-19 type			0.121	0.728
Mild	25	27		
Common	6	8		
Sleep status				
ISI	15.3 (3.9)	15.7 (2.9)	-0.498	0.621
Sleep latency	55.0 (23.0)	52.3 (14.5)	-0.581	0.563
Night sleep duration	5.8 (0.7)	5.7 (0.5)	1.041	0.303
Sleep efficiency	0.78 (0.09)	0.80 (0.08)	0.124	0.228

or COVID-19 type between the two groups ($p>0.05$). There were no statistically significant differences in ISI scores, sleep latency, night sleep duration, or sleep efficiency between the two groups at baseline ($p>0.05$), as shown in Table 1.

Baseline and post-intervention outcomes

The ISI score post-intervention was lower than the ISI at baseline. Sleep latency was significantly shortened at post-intervention; night sleep duration was prolonged at post-intervention; and sleep efficiency was improved after the intervention. The differences were statistically significant ($p<0.05$), as shown in Table 2.

Subjective sleep improvement rate

With the increase of intervention, the rate of subjective sleep improved gradually. After 2 weeks, the subjective good sleep

rate of acute insomnia (83%) was higher than that of chronic insomnia (69%), and the difference was statistically significant ($p<0.05$), as shown in Fig. 1.

Comparison of sleep quality of acute and chronic insomnia from baseline to post-intervention

After the intervention, the ISI score of the AI group was lower than that of the CI group, and the difference was statistically significant ($p<0.05$). Δ (ISI score, sleep latency, sleep time, and sleep efficiency) = post-intervention value minus baseline value which represents the improvement degree of insomnia. Δ ISI score and Δ sleep latency in the AI group were statistically significantly lower than that in the chronic insomnia group ($p<0.05$). There was no significant difference in Δ sleep duration and Δ sleep efficiency between the two groups ($p>0.05$) (see in Table 3).

Use of sedative-hypnotic drug

Throughout the intervention, sedative-hypnotic drugs were alprazolam, eszolam, and eszopiclone. In the AI group, two patients received alprazolam, two patients received eszolam, and one patient received eszopiclone. In the CI group, five patients received alprazolam, six patients received eszolam, and three patients received eszopiclone. The utilization rate of sedative and hypnotic drugs in the AI group was lower than that in the CI group, and the difference was statistically significant ($p<0.05$) (Table 4).

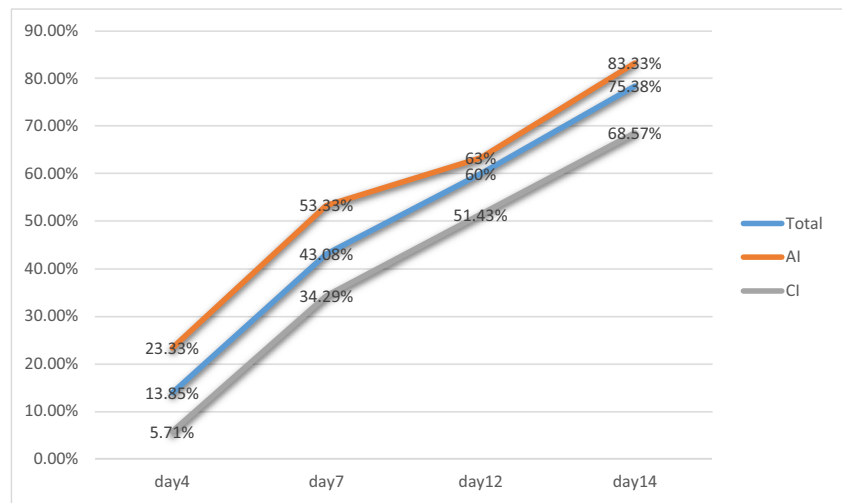
Discussion

The primary goal of this study was to evaluate the efficacy of SCBT-I among women with COVID-19 in a mobile cabin hospital. We found strong support for our hypothesis that SCBT-I treatment would be associated with significant improvement in insomnia symptoms. After the 2-week study period, insomnia severity scores decreased and the rate of subjective sleep improvement increased. In addition, women who received SCBT-I treatment reported great reductions in the amount of time they lay awake in bed and greater improvements in global sleep

Table 2 Comparison of baseline and post-intervention differences on sleep-related indicators

	Baseline	Post-intervention	t	p
ISI	15.5 (3.4)	10.1 (3.7)	10.488	<0.001
Sleep latency(min)	53.6 (18.9)	35.3 (11.2)	10.951	<0.001
Night sleep duration (h)	5.76 (0.58)	6.62 (0.63)	-10.546	<0.001
Sleep efficiency	0.79 (0.08)	0.86 (0.07)	-7.937	<0.001

Fig. 1 Subjective sleep improvement rate



quality including sleep duration and sleep efficiency. The subjects of our study are special, because COVID-19 is highly infectious and requires reduced exposure and less group activity. With group therapy, traditional forms of individual and group CBTI increase risk of infection. Engaging in online or mobile-based interventions is a good option for individuals mastering a self-management approach. S-CBTI utilizes the core content of CBTI, including education and sleep hygiene, stimulus control, and self-guided relaxation training. The intervention also employed innovatively guided patient self-training with the help of the WeChat platform and printed materials. Of note, the high completion rate verified its feasibility in Wuhan Jiangnan Mobile Cabin Hospital. Due to free care for all in the cabin hospital, patients and doctors established a relationship of trust. Therefore, the drop-out rate of this study was very low, with only one patient dropping out after the first day. The overall improvement rate was relatively high.

Another purpose of this study was to assess the effectiveness of S-CBTI, particularly for acute insomnia that occurs during COVID-19. Acute insomnia can be divided into adaptive insomnia, stress insomnia, transient

insomnia, symptom insomnia, and sub-chronic insomnia [26]. CBTI is widely accepted as a first-line treatment for chronic insomnia, but there are few studies on non-drug therapy for acute insomnia. Charlotte Randall and colleagues developed a “one-shot” CBT-I intervention which was effective in managing acute insomnia and mood (depression, anxiety) symptoms in adult men who were prison inmates [20]. In the current study, SCBTI was more effective in patients with acute insomnia than in patients with chronic insomnia. Medications are frequently prescribed for insomnia in the general population, which are associated with an increased risk of respiratory depression. Primary concerns have been that hypnotics reduce upper airway muscle activity and delay arousal from sleep, leading to worsening of upper airway stability and increased respiratory event duration and hypoxemia [27]. Sedative and hypnotic drugs should be used in COVID-19 patients with caution. The acute insomnia group had a lower utilization rate of sedative and hypnotic drugs, but the insomnia symptoms, especially the improvement of falling asleep, fully demonstrated the effectiveness of S-CBTI in treating acute insomnia in COVID-19 patients. We believe this study revealed that women with COVID-19 are highly interested in psychotherapy for insomnia.

Table 3 Comparison of change from baseline to post-intervention of acute and chronic insomnia

	AI (n=31)	CI (n=35)	t	p
Post-intervention ISI	9.0 (3.7)	11.8 (3.2)	-3.326	0.001
ΔISI	-6.3 (4.3)	-3.9 (3.1)	2.620	0.011
Δ sleep latency	-22.7 (15.6)	-14.7 (10.6)	2.412	0.019
Δ sleep duration	0.92 (0.66)	0.81 (0.68)	-0.637	0.526
Δ sleep efficiency	0.07 (0.06)	0.05 (0.06)	-0.943	0.349

Table 4 Comparison of the usage of sedative-hypnotic drug between AI and CI

	AI (n=31)	CI (n=35)	χ ²	p
Use of sedative-hypnotic drug	5	14	4.569	0.033
Non-use of sedative-hypnotic drug	26	21		

Limitations

Due to practical operability and ethical issues, there were no control subjects enrolled in the study. No assessment of emotional and pneumonia-related symptoms was performed, so we were not able to analyze whether or not emotional factors and COVID-19 symptoms influenced the severity of insomnia and effectiveness of therapy. The subjects of this study were all women, and the particularity of the population should be considered when applied to other groups. The remission of insomnia symptoms in acute insomnia may be partially attributable to spontaneous remission. The effect of a psychological suggestion should also be considered in this study. When patients feel they are valued, their confidence in treatment increases. Long-term follow-up can be conducted in the future to understand the long-term effect of S-CBTI.

Declarations

Ethical approval This study was approved by the Ethics Committee of the First Affiliated Hospital of Zhengzhou University (Ethics Number: 2020-Ky-119).

Informed consent Informed consent was obtained from all individual participants included in the study.

Conflict of interest The authors declare no competing interests.

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