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Original Article

Chronic repetitive transcranial magnetic stimulation (rTMS) on sleeping quality and mood status in drug dependent male inpatients during abstinence

Jian Lin [a, 1], Xiaoli Liu [b, c, d, 1], Hailong Li [a], Liling Yu [a], Miaosen Shen [e], Yongjin Lou [e], Shuzhen Xie [f], Jie Chen [e], Rui Zhang [a, **], Ti-Fei Yuan [c, g, *]

[a] Department of Rehabilitation Medicine, Zhejiang Hospital, Hangzhou, Zhejiang, China
[b] Ningbo Kangning Hospital, Ningbo, Zhejiang, China
[c] Shanghai Key Laboratory of Psychotic Disorders, Shanghai Mental Health Center, Shanghai Jiaotong University School of Medicine, Shanghai, China
[d] School of Psychology, Nanjing Normal University, Nanjing, Jiangsu, China
[e] Fuchun Addiction Rehabilitation Center, 1 Heshangling Road, Fuyang, Hangzhou, Zhejiang, China
[f] Gudang Community Health Service Center, Hangzhou, Zhejiang, China
[g] Co-innovation Center of Neuroregeneration, Nantong University, Nantong, Jiangsu, China

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ABSTRACT

Background: Drug abstinence is accompanied by aversive experiences and lasting changes in mood status and worsening sleep quality. This study investigated the potential effects of chronic repetitive transcranial magnetic stimulation (rTMS) in substance dependent inpatients during abstinence.
Methods: This was a double-blinded study with 105 males inpatients dependent on heroin or methamphetamine (average abstinence time was six months). The inpatients were randomly divided into 10 Hz intervention (n = 40), sham stimulation (n = 40) and control (waiting list, no treatment) (n = 25) groups. Five sessions of rTMS stimulation were administrated for six consecutive weeks, reaching a total of 180,000 pulses. There was no intervention for control group. Patients were assessed using the Pittsburgh Sleep Quality Index (PSQI), Self-rating Anxiety Scale (SAS) and Self-rating Depression Scale (SDS) were assessed prior to and after six weeks of intervention.
Results: The results showed that six weeks of rTMS treatment significantly improved the sleep quality ($p < 0.001$), alleviated depression ($p < 0.001$) and anxiety state ($p < 0.001$) of substance dependent inpatients in early abstinence. Furthermore, the active TMS group showed significant differences between sham and control groups.
Conclusion: These findings suggested that chronic rTMS treatment have positive effects for substance dependent inpatients during abstinence. Future studies are required to understand the underlying mechanism for improving different clinical symptoms.

1. Introduction

Drug addiction is a chronic brain disorder, which is associated with neuronal structural and functional changes, as well as the compulsive drug-seeking behavior [1]. During the habit-forming addictive behavior, the mesolimbic dopaminergic system, hippocampus and amygdala were progressively recruited in different phases of “dark” learning [2]. Several neuroimaging approaches have identified different cortical networks that are related to addiction, especially the prefrontal cortex [3], contributing to different aspects of addiction syndrome.

* Corresponding author. Shanghai Key Laboratory of Psychotic Disorders, Shanghai Mental Health Center, Shanghai Jiaotong University School of Medicine, Shanghai, China.
** Corresponding author. Department of Rehabilitation Medicine, Zhejiang Hospital, 1229, Gudun Road, Hangzhou, Zhejiang, China.
E-mail addresses: Drzhangrui@163.com (R. Zhang), ytf0707@126.com (T.-F. Yuan).
[1] JL and XL contributed equally.

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Acute abstinence (ie, few days) from addictive drugs resulted in acute aversive experiences and somatic symptoms. In the later period of abstinence (ie, from few weeks to few months), drug abusers exhibited sleep disorders, long-lasting anxiety and depressive behaviors [4–7]. Antidepressants and vitamins are common pharmacological agents adopted for improving disrupted sleep and mood status [8]. These interventions could modulate cortical excitability and subsequently the cortical network functions, implying that direct neuro-modulation (with non-invasive brain stimulation) might improve the sleep quality during abstinence as well.

Transcranial magnetic stimulation (TMS) has been considered as an important tool to measure cortical functions and differentiate the pathophysiology underlying distinct sleep disorders [9–11]. Repetitive TMS (rTMS) is also considered as a prospective tool for sleep enhancement or is considered as a modulating tool during sleep [12–15]. In addition to the antidepressive effects of rTMS [16–21], its stimulation over left dorsolateral prefrontal cortex (DLPFC) has proved to reduce the craving for substance, alleviating the drug intake [22–26].

The efficacy of rTMS has been proved for different symptoms; however, it is unclear if it is useful for treating lasting sleep disruptions in substance abuse patients. Therefore, this present study aimed to investigate whether rTMS stimulation over DLPFC could improve sleep quality and mood disruption in a group of male substance dependence inpatients.

2. Methods

This was a double-blinded study, wherein the psychologist was responsible for evaluating the questionnaire procedures and the subjects were blinded to the treatment groups (sham and active groups). One senior physician was appointed as incharge of randomization and rTMS manipulation.

2.1. Subjects

A total of 105 male inpatients were recruited from Fuchun Addiction Rehabilitation Center in the present study (right-handed, aged 17–51 years old). The drug dependence diagnosis was based on a clinical interview by an experienced psychiatrist according to the DSM-IV criteria. The inclusion criteria were as follows: (1) the subjects should complete physiological detoxification (eg, abstinence from drugs, including methadone for six months, morphine urine test and naloxone test negative); (2) no longer have acute somatic symptoms; should have normal blood, urine routine, liver and kidney function tests; (3) should have no obvious mental disorders, personality disorders and other psychosocial impairment; and (4) no other major infectious diseases, such as AIDS, syphilis, etc.

Subjects were excluded if they had history of severe mental illness, epilepsy, and traumatic brain injury. Furthermore, rTMS was used in the present study, and therefore, the subjects with atypical Parkinsonism syndrome including autonomic failure, pyramidal signs, cerebellar signs, gaze palsy, severe dysarthria or myoclonus were also excluded. The study was approved by the ethics committee of Zhe Jiang Hospital, and written informed consent was obtained from all subjects prior to the study.

The operator assigned each subject a computer-generated random number for determining group allocation according to drug dependence type and treatment group and was as follows: intervention (n = 40), sham (n = 40) and control group receiving no additional intervention (n = 25) (Fig. 1).

2.2. rTMS procedures

The participants were seated comfortably in a chair, and electromyography recorded the abductor pollicis brevis muscle. Single-pulse TMS was administered to the primary motor cortex (M1) by "8"-shaped coil (CCY-I TMS instrument, Yiruide Co., Wuhan, China) to measure the rest motor threshold (RMT), and was determined by the lowest intensity generated motor evoked potentials (MEPs) that are >50 μV in five of 10 trials. In this study, 10 Hz rTMS at 100% RMT (5-sec on, 10-sec off for 10 min, 40 trains leading to a sum of 2000 pulses) of rTMS was applied over left DLPFC (located with EEG 10/20 system) (CCY-I TMS instrument, Yiruide Co, Wuhan, China) per session every morning as previously described [26]. The coil was in a figure eight shape. The temperature of the coil was shown on the screen. The automatic alarm turns on and the machine stops when the temperature was above 40°.

The participants were asked to sit comfortably on a chair, and the surface electrodes were placed on the thenar muscle. In addition, a ground electrode was attached at the elbow joint. If the minimum stimulus intensity when the amplitude of the evoked wave was greater than 50 μV for at least five times out of 10 stimuli was then considered as the resting motor threshold (rMT) and "hot spot" [27]. For sham stimulation, the left DLPFC was located in F3 (EEG 10/20 system) and the coil was rotated 90° vertical to the skull surface. The treatment was repeated for five consecutive days per week (on weekdays) and lasted for six weeks. Pittsburgh sleep quality index (PSQI), self-rating anxiety scale (SAS) and self-rating depression scale (SDS) were measured at baseline (T_0) and after six-week intervention (T_{6w}).

2.3. PSQI-Chinese version

The Chinese PSQI version was employed [28,29] which consisted of 19 self-rated items in seven components: subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbance, use of sleep medication and daytime dysfunction. Each component was graded by 0–3. The higher score indicates worse sleep quality, and a global score >5 indicates poor sleep with a sensitivity of 89.6–98.7% and a specificity of 84.4–86.5% [30].

2.4. SAS-Chinese version

The SAS is widely used in varied occupations, cultural classes and age groups of normal people or patients with various diseases [31]. The scale consists of 20 items, where items 1–5 are mainly about anxiety, fear and unfortunate feelings; items 6–10 are about physical pain, and palpitation; 11–15 are dizziness and dyspnea; and 16–20 are mainly frequent urination and sweating symptoms. Each item was given a score based on a Likert-type scale of 1–4 (based on these replies: "a little of the time," "some of the time," "good part of the time," and "most of the time"). The total raw scores range from 20 to 80. The score of 20–44 is considered normal; 45–59 is mild to moderate anxiety levels; 60–74 indicates severe anxiety levels and 75–80 as extreme anxiety levels.

2.5. SDS-Chinese version

SDS included 20 items [32]. Of these, two items are about psycho-emotional symptoms, eight items for somatic disorders, two items for psychomotor disorders, and the other eight items are on depressive disorders. Each item is scored based on a Likert-type scale of 1–4 (based on these replies: "a little of the time," "some of the time," "good part of the time," and "most of the time"). The total raw scores ranged from 20 to 80. The score of 20–44 is considered

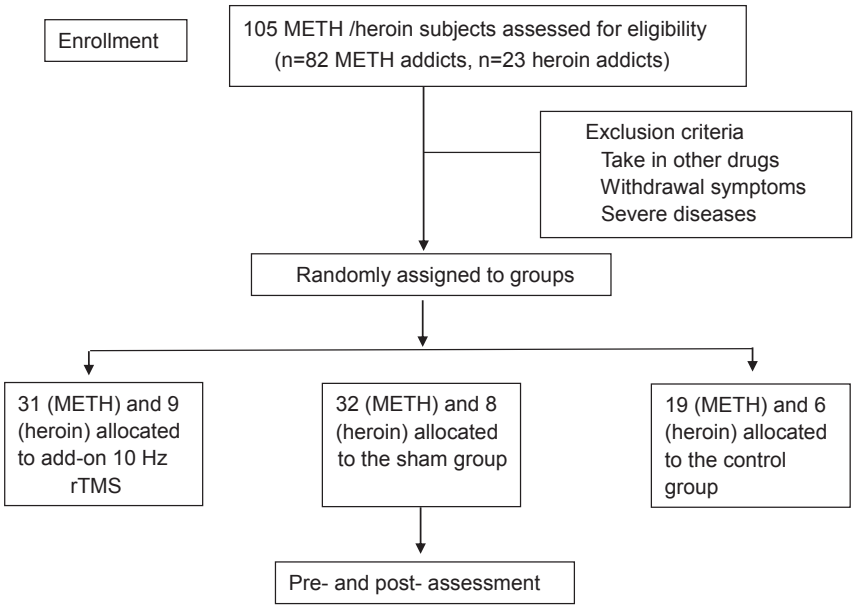

Fig. 1. Flowchart of the study. A total of 105 subjects (82 METH patients and 23 heroin patients) were enrolled in the study, and were randomized into three groups. The operator using a computer-generated random number assigned each subject into a group, which included intervention (n = 40), sham (n = 40) and control group receiving no additional intervention (n = 25).

as normal range; 45–59 is mildly depressed; 60–69 indicates moderately depressed, and 70 and above as severely depressed.

2.6. Evaluation of adverse reactions

All the subjects were assessed for adverse reactions after rTMS treatment based on clinical manifestations such as headache, nausea, and epileptic seizures. The operator asked questions based on uncomfortable signs (such as headaches, neck pain, nausea, etc.) at the end of every rTMS session.

2.7. Statistical analysis

All data analysis was performed using SPSS v. 21(IBM Corp., NY, USA). One-way ANOVA and Chi-square test were used to compare the differences in the participant characteristics of the three groups. Through two (baseline, post-treatment) *3 (active, sham, control) repeated ANOVA, the effects of rTMS on PSQI/SDS/SAS were compared. If the main effect or interaction effect was significant, then simple effect analysis with Bonferroni correction was performed, and 0.05 was divided by 9 to generate the p-value for deciding statistical significance. Spearman correlation analyses were used to explore the associations of the score changes in each scale. The overall statistical significance threshold was set as two-tailed, $p < 0.05$.

3. Results

3.1. Characteristic of participants

The demographic and clinical data of the three groups were presented in Table 1. All participants recruited in the present study after 2–4 months of enrollment in the rehabilitation center. We compared the demographic variables of subjects and the results showed no significant differences among the three groups in terms of age, employment, education etc. ($p > 0.05$). There were some baseline differences between the three groups in PSQI ($F_{(2, 102)} = 18.58$, $p < 0.001$) and SDS ($F_{(2, 102)} = 4.923$, $p = 0.009$), with the active TMS group was associated with better sleep quality and depression state than sham TMS (Mean Difference (intervention-sham) = −1.825, SE = 0.30, $p < 0.001$ and Mean Difference (intervention-sham) = 3.20, SE = 1.20, $p = 0.027$, respectively), sham TMS group worse sleep quality than control (Mean Difference (sham-control) = −1.02, SE = 0.34, $p = 0.011$), control group better anxiety state than sham (Mean Difference (sham-control) = −3.64, SE = 1.37, $p = 0.027$). There was no significant difference between control group and intervention group in PSQI and SDS. (Mean Difference (control-intervention) = 0.81, SE = 0.34, $p = 0.059$ and Mean Difference (control-intervention) = 0.44, SE = 1.37, $p = 1.000$, respectively). There was no significant difference in SAS among the three groups ($F_{(2, 102)} = 1.145$, $p = 0.322$) (See Table 1).

3.2. Effect of rTMS on PSQI scores

The main effect of time ($F_{(1, 102)} = 148.57$, $p < 0.001$, $\eta_{p2} = 0.593$) and interaction effect of the groups (intervention, sham, control) * time (T0, T6w) ($F_{(2, 102)} = 204.29$, $p < 0.001$, $\eta_{p2} = 0.800$) showed significant differences. These results suggested that the active rTMS showed significant improvement in sleep quality at T6w ($F = 625.4$, $p < 0.001$), control group showed significant worsening than baseline ($F = 4.678$, $p = 0.033$), and no difference in sham group ($F = 0.731$, $p = 0.395$) (See Table 2).

3.3. Effect of rTMS on SAS scores

The effect of rTMS on SAS scores revealed a significant main effect of time ($F_{(1, 102)} = 265.81$, $p < 0.001$, $\eta_{p2} = 0.723$), as well as the effect of interaction effect of all groups (intervention, sham, control) * time (T0, T6w) ($F_{(2, 102)} = 237.83$, $p < 0.001$, $\eta_{p2} = 0.823$). By simple effect analysis, the SAS scores of intervention group was markedly lowered at T6w ($F = 820.65$, $p < 0.001$) than baseline, and showed no significant differences in both sham ($F = 0.111$, $p = 0.740$) and control groups ($F = 2.387$, $p = 0.125$) at T6w (See Table 2).

Table 1
Demographic and clinical subject data (Mean ± SD).

	Intervention (n = 40)	Sham (n = 40)	Control (n = 25)	F/Chi-Square value	p
Age (year)	33.95 ± 7.13	34.5 ± 8.54	38.56 ± 8.81	2.76	0.068
Employment (employed/unemployed)	23/17	18/22	12/13	1.33	0.514
Education (year)	9.18 ± 2.17	9.65 ± 2.76	9.08 ± 3.04	0.43	0.651
Relapse time	2.75 ± 1.00	2.55 ± 1.04	2.92 ± 1.35	13.14	0.359
Marriage (unmarried/marriage/divorced)	19/15/6	19/11/10	9/10/6	2.56	0.634
Age at first intake addictive substance	25.65 ± 7.26	27.46 ± 8.36	29.64 ± 9.07	1.64	0.199
Abstinence time (day)	197.10 ± 16.87	189.23 ± 14.31	190.08 ± 15.17	0.049	0.952
Year of addiction	8.30 ± 0.81	7.15 ± 0.73	8.92 ± 1.22	1.00	0.371
METH/heroin	31/9	32/8	19/6	0.157	0.924
PSQI (Baseline)	10.95 ± 1.34	12.78 ± 1.25	11.76 ± 1.48	18.58	<0.001
SAS (Baseline)	56.60 ± 4.31	57.98 ± 5.51	58.60 ± 7.18	1.145	0.322
SDS (Baseline)	63.80 ± 4.45	60.60 ± 5.33	64.24 ± 6.65	4.923	0.009

Note: METH, methamphetamine; rMT, resting motor threshold; PSQI, Pittsburgh Sleep Quality Index; SAS, Self-Rating Anxiety Scale; SDS, Self-Rating Depression scale.

3.4. Effect of rTMS on SDS scores

The effect of rTMS on SDS scores revealed that the main effect of time ($F_{(1, 102)} = 196.77$, $p < 0.001$, $\eta_{2p} = 0.659$) and interaction effect of all groups (intervention, sham, control) * time (T0, T6w) ($F_{(2, 102)} = 428.78$, $p < 0.001$, $\eta_{2p} = 0.894$) were significant. The subjects showed an improved depressive state after six-weeks of active treatment ($F = 1142.56$, $p < 0.001$). On the contrary, the outcomes indicated that the subjects in sham and control groups had worsened depressive mood than baseline ($F = 6.724$, $p = 0.011$, $F = 13.19$, $p < 0.001$, respectively) (See Table 2).

3.5. Correlation analyses between changes in PSQI/SDS/SAS scores

After Spearman correlation analyses, for add-on intervention group, the delta PSQI score was significantly correlated with delta SAS score ($r = 0.514$, $p = 0.001$) and delta SDS score ($r = 0.368$, $p = 0.02$), but there was no correlation between delta SAS and SDS score ($r = 0.242$, $p = 0.133$). For sham group, only delta PSQI showed a positive association with delta SDS ($r = 0.358$, $p = 0.024$), and then the delta SAS was not correlated with delta SDS ($r = 0.046$, $p = 0.778$) and delta PSQI ($r = 0.214$, $p = 0.185$). For control group, no positive correlation was observed between delta PSQI and delta SAS ($r = 0.228$, $p = 0.273$)/delta PSQI and delta SDS ($r = 0.22$, $p = 0.291$)/delta SDS and delta SAS ($r = -0.31$, $p = 0.131$) (Fig. 2).

3.6. Adverse reaction

Four subjects (three in intervention group and one in sham group, and none in control group) reported mild dizziness or scalp pain after the first two sessions. The symptoms were relieved within 2 h, and had no other symptoms. No subjects have quit the study due to adverse reactions.

Table 2
Effect of rTMS on PSQI, SAS, and SDS in 3 groups (Mean ± SD).

	T_0	T_{6w}	F	p
PSQI				
Intervention	10.95 ± 1.34	8.03 ± 0.83	625.40	<0.001
Sham	12.78 ± 1.25	12.68 ± 1.19	0.731	0.395
Control	11.76 ± 1.48	12.08 ± 1.38	4.678	0.033
SAS				
Intervention	56.60 ± 4.31	50.15 ± 3.29	820.65	<0.001
Sham	57.98 ± 5.51	57.90 ± 5.47	0.111	0.740
Control	58.60 ± 7.18	58.16 ± 6.92	2.387	0.125
SDS				
Intervention	63.80 ± 4.45	54.68 ± 3.58	1142.56	<0.001
Sham	60.60 ± 5.33	61.30 ± 5.14	6.724	0.011
Control	64.24 ± 6.65	65.48 ± 6.21	13.19	<0.001

Note: PSQI, Pittsburgh Sleep Quality Index; SAS, Self-Rating Anxiety Scale; SDS, Self-Rating Depression scale.

4. Discussion

In the present study, we reported that high-frequency (10 Hz) rTMS over left DLPFC significantly reduced PSQI, SAS and SDS scores

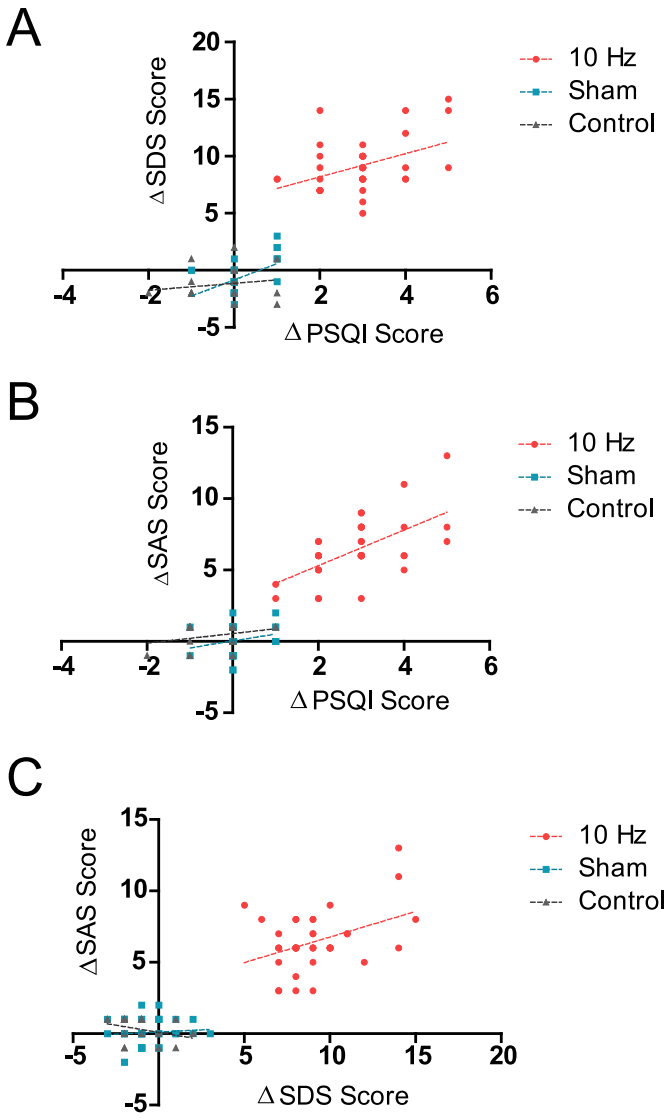

Fig. 2. Correlation analyses between delta PSQI/SDS/SAS score (Baseline-Week 6). Pittsburgh Sleep Quality Index (PSQI)-Chinese version; Self-Rating Anxiety Scale (SAS)-Chinese version; Self-Rating Depression scale (SDS)-Chinese version.

in a group of male inpatients with substance abuse suffering from sleep disruption during abstinence period. Sleep and mood disruptions are common symptoms seen during drug abstinence, and these potentially attribute to the altered neurochemical signaling in the brain [3,5,33,7]. TMS treatment is known to enhance monoamine signaling in the brain, and might re-balance the above changes induced by abstinence [34]. In addition, TMS stimulation induces sleep-like slow waves in the brain [35,36], facilitating the formation of oscillation during sleep. Chronic TMS stimulation rebalances the peripheral-central nervous system interactions and modifies the cortical excitability [37,38]. While the underlying mechanisms of neural network re-organization still require neuroimaging evidences.

Together with improved sleep quality, TMS treatment alleviated anxiety and depression scores in our study subjects. Notably, the changes in PSQI scores were significantly correlated with changes in SAS and SDS scores. Previous studies reported that sleep disruption is associated with mood status, and mood disorders are associated with insomnia [39,40]. The neural circuit mechanisms underlying the simultaneous changes are yet to be investigated. It is noted that the 180,000 pulses over six weeks treatment yielded a modest (around 20%) decrease in the depression score, which was not comparable to other TMS studies on depression subjects (less pulses, such as 63,000 pulses for more than 40% decrease) [16,37,17]. The potential discrepancies between abstinence associated depression and major depression require further investigation in future studies.

Of the 80 subjects, four in intervention/sham group reported headache and dizziness, and were relieved within 2 h without any treatment. There were no serious adverse reactions during the intervention, suggesting that rTMS is a safe and effective non-drug intervention that improves anxiety, depression and sleep status in patients at early abstinence. The rate of adverse effects was comparably lower when compared to other rTMS studies, and is worth to investigate further in future.

Heroin (opiate type) and methamphetamine (psychostimulant type) abuse are distinct in acute pharmacology, neurobiology, environment setting of dependence, gender discrepancy in relapse, etc. [41]. On the other hand, during the chronic processes of addiction behavior formation, a shared neural mechanism has been emerged, such as the adaptation of prefrontal cortical network [3]. In future, it remains to be very interesting to analyze the potential response differences to different TMS frequencies for individual TMS therapy (eg, with EEG based prognosis).

However, there were several limitations in the present investigation. First, due to the inclusion of sample sizes, significant group differences were observed in the baseline scores of PSQI and SDS. Second, the study is limited by six weeks of intervention, and the long-lasting effect is not examined. Follow-up study with potential relapse measurement might offer important information regarding this. Third, the neuroimaging approaches or electrophysiological recordings could provide mechanistic explanations regarding the TMS efficacy for different clinical symptoms, and the interactions between sleep regulating and mood regulating regions. Fourth, the rehabilitation center includes physical exercise program for all subjects, which could have an effect on mood or sleep improvement continuously in all the groups. Finally, the trial did not measure the self-report craving or other objective measures to sleep quality, as this is considered as important for addiction-related study.

In the present study, we only assessed the effect of high frequency rTMS on sleep disorder and further studies with other frequencies should be tested. In future, it is worth interesting to perform navigated TMS treatment on different cortical regions in order to probe the sleep regulating power of TMS stimulation.

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Conflict of interest

None declared from all authors.

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