


# BMJ Open Acupuncture combined with cognitive-behavioural therapy for insomnia (CBT-I) in patients with insomnia: study protocol for a randomised controlled trial

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## ABSTRACT

**Introduction** Insomnia affects physical and mental health due to the lack of continuous and complete sleep architecture. Polysomnograms (PSGs) are used to record electrical information to perform sleep architecture using deep learning. Although acupuncture combined with cognitive-behavioural therapy for insomnia (CBT-I) could not only improve sleep quality, solve anxiety, depression but also ameliorate poor sleep habits and detrimental cognition. Therefore, this study will focus on the effects of electroacupuncture combined with CBT-I on sleep architecture with deep learning.

**Methods and analysis** This randomised controlled trial will evaluate the efficacy and effectiveness of electroacupuncture combined with CBT-I in patients with insomnia. Participants will be randomised to receive either electroacupuncture combined with CBT-I or sham acupuncture combined with CBT-I and followed up for 4 weeks. The primary outcome is sleep quality, which is evaluated by the Pittsburgh Sleep Quality Index. The secondary outcome measures include a measurement of depression severity, anxiety, maladaptive cognitions associated with sleep and adverse events. Sleep architecture will be assessed using deep learning on PSGs.

**Ethics and dissemination** This trial has been approved by the institutional review boards and ethics committees of the First Affiliated Hospital of Sun Yat-sun University (2021763). The results will be disseminated through peer-reviewed journals. The results of this trial will be disseminated through peer-reviewed publications and conference abstracts or posters.

**Trial registration number** CTR2100052502.

## INTRODUCTION

Insomnia is characterised by difficulties in initiating or maintaining sleep or impaired daytime functioning, which impact both physical and mental health.<sup>1-3</sup> The lack of continuous and complete sleep architecture due to long-term fragmented and light sleep in patients with insomnia causes a decrease in sleep quality, which affects daily functions, and even induces anxiety, depression and other

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study will investigate the efficacy and effectiveness of electroacupuncture combined with cognitive-behavioural therapy for insomnia (CBT-I).
- ⇒ We will use deep learning to observe the effects of electroacupuncture combined with CBT-I on sleep architecture in different dimensions.
- ⇒ The efficacy and effectiveness of electroacupuncture on sleep quality and sleep beliefs and attitudes of patients with insomnia will be further studied in the future.
- ⇒ Although we explained the randomised design and statistical analysis through intention-to-treat analysis and sensitivity analysis to some extent, systematic errors and bias remained uncertain.

mental symptoms.<sup>4-6</sup> With the increasing pressures in daily life and work, insomnia is becoming a public health problem that needs to be solved urgently as it worsens the quality of life of patients, burdens caregivers, and increases social and economic costs.<sup>7-9</sup>

Cognitive-behavioural therapy for insomnia (CBT-I) is recommended as first-line treatment for insomnia and may improve sleep quality and alleviate poor sleep cognition in patients with insomnia.<sup>10-12</sup> During the early stage of treatment, the sleep quality of patients with severe anxiety were improved slowly and the compliance of these patients were poor. Thus, as confirmed in previous studies, acupuncture combined with CBT-I could not only solve anxiety, depression and other emotions caused by insomnia but also ameliorate poor sleep habits and detrimental cognition.<sup>13-16</sup>

However, there is a lack of rigorous clinical evidence on the treatment of insomnia with acupuncture combined with CBT-I; moreover, the clinical mechanism is unclear. In previous studies, we found that by analysing

polysomnograms (PSGs), electroacupuncture improves sleep architecture and prolongs the duration of slow-wave and rapid-eye-movement (REM) sleep.<sup>17–19</sup> But whether acupuncture combined with CBT-I improves sleep architecture requires further research.

During the past decade, the application of deep learning to automatic sleep staging using PSGs has shown promise for understanding the macrostructure of sleep. Deep learning allows the automatic extraction of features from data related to classification tasks, and the performance of deep neural networks continues to improve as the size of the dataset increases.<sup>20–22</sup>

Using a high-performance automatic sleep staging algorithm to analyse PSGs recordings via deep learning, this study will focus on the effects of electroacupuncture combined with CBT-I on sleep architecture, sleep quality, and sleep attitudes and beliefs in patients with insomnia. Furthermore, this research will provide guidance for electroacupuncture combined with CBT-I using artificial intelligence.

## METHODS

### Study design

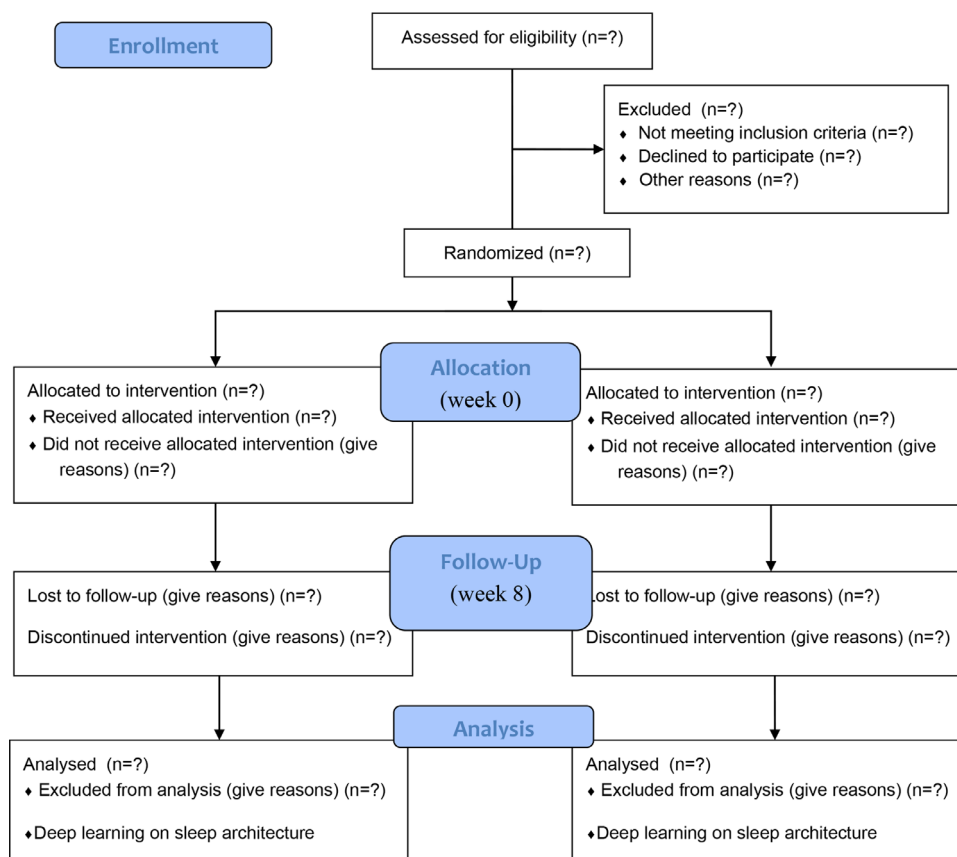
The study will be an assessor-blinded, randomised controlled trial. The protocol was approved by the ethics committee of the First Affiliated Hospital of Sun Yat-sun University (2021763). We will follow the Consolidated Standards of Reporting Trials and Standards for

Reporting Interventions in Clinical Trials of Acupuncture guidelines for the design and reporting of the trial.<sup>23 24</sup> The flow chart of the trial is presented in [figure 1](#), and the schedule of enrolment, interventions and outcome assessments are presented in [table 1](#).

Sample size calculations, referring to the previous literature,<sup>25</sup> we assume that the expected Pittsburgh Sleep Quality Index (PSQI) value of the observation group is  $9.45 \pm 1.84$  and the control  $6.43 \pm 2.10$ . We determine that a sample size of 11 per group would provide a power of 90% and an alpha level of 0.05, which would allow us to detect a difference in PSQI score between the two groups. Allowing for a 20% drop-out rate, a sample size of 30 in each group is sufficient to meet statistical requirements.

### Randomisation, allocation and blinding

Patients who are interested in participating in the trial will initially be screened by phone and then asked to participate in a face-to-face interview to conduct further surveys. After recruiting all participants, random numbers will be generated and assigned by a central randomisation system of the Clinical Research and Data Center of Guangzhou University of Chinese Medicine. The researcher who will screen the eligible patients after baseline will assign patients to either the treatment or control group. Researchers, which include statisticians, outcome assessors and data analysts, will all be blinded to patients' group assignments. Although acupuncturists will be not blinded to group assignment, they will not be involved



**Figure 1** CONSORT 2010 flow diagram. CONSORT, Consolidated Standards of Reporting Trials.

**Table 1** Research flow chart

Project	Screening	Observation phase			Follow-up phase	
	Assession 0 pre-treatment	Assession 1 pre-treatment	Assession 2 Week 2±1 day	Assession 3 Week 4±2 day	Assession 4 Week 8±2 day	Unplanned follow-up
Medical history collection	√	-	-	-	-	
Sign the informed consent form	√	-	-	-	-	
Inclusion criteria	√	-	-	-	-	
Exclusion criteria	√	-	-	-	-	
Basic Information	√	-	-	-	-	
Vital signs	√	√	√	√	√	✘
Index of laboratory inspection	✘	✘	✘	✘	✘	
PSG	-	√	-	√	-	
Pittsburgh Sleep Quality Index	-	√	√	√	√	
Beck depression inventory	-	√	√	√	√	
Beck anxiety inventory	-	√	√	√	√	
DBAS-16	-	√	√	√	-√	
Adverse events	-	✘	✘	✘	✘	✘
Medication records	-	√	√	√	√	
Terminate test evaluation	-	✘	✘	✘	✘	

Notes: "✘" Record when necessary.

DBAS-16, Dysfunctional Beliefs and Attitudes about Sleep Scale 16 version; PSG, polysomnogram.

in outcome assessments or data analyses. In addition, all researchers will undergo training for specific procedures before the trial begins.

### Participants and recruitment

Patients will be recruited using hospital-based advertisements in the Department of Acupuncture and Department of Neurology of the First Affiliated Hospital of Sun Yat-sen University from January 2022 to December 2025.

The inclusion criteria will be as follows: (1) meets diagnostic criteria for insomnia based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition<sup>26</sup> and the International Classification of Sleep Disorders, Third Edition,<sup>27</sup> (2) aged 18–65 years, (3) experienced insomnia for more than 1 month but less than 2 years before the start of the trial and (4) voluntarily agrees to participate in the investigation and provides written informed consent before the clinical trial starts.

The exclusion criteria will be as follows: (1) serious cardiovascular, liver, kidney or haematopoietic system disease, (2) insomnia was caused by a nervous system disease (eg, stroke or Parkinson's disease), (3) insomnia was caused by a mental disorder, such as depression or anxiety, (4) history of sleep apnea, (5) pregnant or lactating women and (6) have received or currently receiving CBT-I.

Withdrawal criteria will be as follows: (1) patient withdrawal from the trial because of personal reasons, (2) patient has an adverse reaction related to acupuncture and refuses to continue treatment, (3) during the follow-up period, the patient cannot be contacted because of change of address and telephone number.

### Intervention

The intervention will begin the day following randomisation. All participants will receive 20 times treatments (5 times per week for 4 weeks).

### Observation group

#### Acupuncture treatment

Patients' skin will be disinfected with 75% alcohol, and patients will be asked to lie supine and wear eye masks for a better curative effect. Each participant will receive acupuncture treatment from the same acupuncturist who has more than 5 years of clinical experience in acupuncture therapy. The temperature of the treatment room will not be lower than 25°C.

Patients in the acupuncture group will receive electroacupuncture treatment on Sishenchong (EX-HN1), bilateral Neiguan (PC6), bilateral Taixi (KI3), bilateral Shenmen (HT7) and bilateral Sanyinjiao (SP6).<sup>28</sup> Tube-guided acupuncture needles will be inserted to a depth

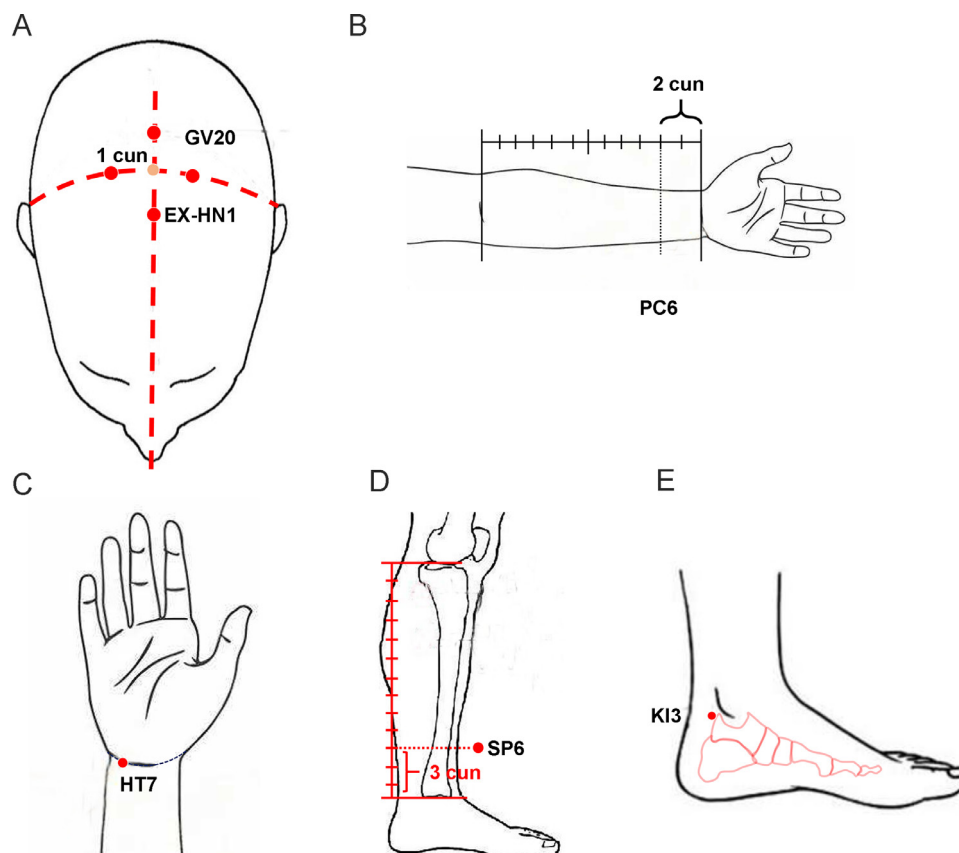
**Table 2** Acupuncture location and method for each acupoint

Acupoint	Location	Needling method
Sishenchong (EX-HN1)	On the parietal region, 1 cun anterior, posterior and lateral to Baihui, 4 acpoinits totally.	The angle between the needle tip and the scalp is 30°. Move the needle tip backward along the anterioreposterior midline, and then insert the needle 0.5 cun.
Neiguan (PC6)	On the line joining Daling and Quze, between the tendons of palmaris longus and flexor carpi radialis, 2 cun above the transverse crease of the wrist.	Puncture perpendicularly 1–1.5 cun.
Taixi (KI3)	In the depression between the tip of the medial malleolus and the Achilles tendon.	Puncture perpendicularly 0.5–1 cun.
Shenmen (HT7)	On the palmar ulnar end of the transverse crease of the wrist, and on the radial aspect of the tendon of the ulnar flexor m. of the wrist.	Puncture perpendicularly 0.5–1 cun.
Sanyinjiao (SP6)	Posterior to the mesial border of the tibia, and three cun above the tip of the medial malleolus	Puncture perpendicularly 1–1.5 cun.

of 17–25 mm at each acupoint (acupuncture location and method for each acupoint are provided in [table 2](#) and [figure 2](#). A low-frequency electronic pulse therapy instrument (G6805-2A, Shanghai Huayi Medical Instrument, Shanghai, China) will be used with 10Hz continuous waves, and the current will range from 1 to 5 mA, which will be adjusted based on the tolerance of each patient.

#### CBT-I treatment

CBT-I treatment will be given while acupuncture treatment is in progress. The intervention will consist of behavioural components (eg, sleep restriction and stimulus control), cognitive components (eg, cognitive restructuring and paradoxical intention), progressive muscle relaxation and sleep hygiene.<sup>29</sup>

**Figure 2** Location of acupoints.

### Control group

The procedure for the control group will be the same as that for the observation group with no CBT-I treatment. The major difference in interventions between the two groups being the tube needling method, in which no needle will be inserted through the tube for patients in the control group. To mimic the sensation of a real needle being inserted into the body, the acupuncturist will place the tube close to the skin at the acupoint and tap the top of the tube.

### Quality control

The trial will be conducted under the supervision of the First Affiliated Hospital of Sun Yat-sun University. A qualified clinical trial expert will be invited to monitor the study to identify problems during the trial, examine collected data and control bias.

### Outcome measures

#### Primary outcome

##### *Pittsburgh Sleep Quality Index*

The PSQI is an internationally established tool that is used to evaluate sleep quality. The scale includes seven dimensions that consist of subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, sleeping medication and daytime dysfunction. The score correlates adversely with sleep quality which a higher score means the sleep quality is worse, and each factor has a score of 0–3 to provide a total score of 21 points.<sup>30 31</sup>

#### Secondary outcomes

##### *The Beck Depression Inventory*

The Beck Depression Inventory (BDI) is a valid self-assessment index to measure depression severity and consists of 13 items. Each item is scored from 0 to 3 (0–4 indicates no depression, 5–7 indicates mild depression, 8–15 indicates moderate depression), with a score of 16 points or more considered as severe depression.<sup>32–34</sup>

##### *The Beck Anxiety Inventory*

The Beck Anxiety Inventory (BAI) is used to assess the degree of anxiety and consists of 21 items scored from 1 to 4 (15–25 points indicates mild anxiety, 26–35 points indicates moderate anxiety and 36 points is considered severe anxiety).<sup>35 36</sup>

##### *The Dysfunctional Beliefs and Attitudes about Sleep Scale 16 version*

The Dysfunctional Beliefs and Attitudes about Sleep Scale 16 version (DBAS-16) is used to evaluate maladaptive cognitions associated with sleep. There are 16 items in the index, which are divided into four factors comprising consequences of insomnia, worry about sleep, sleep expectations and medication. These factors are scored on a scale of 1–5 (strongly disagree to strongly agree). The total score is positively correlated with the reasonableness of sleep beliefs and attitudes.<sup>37 38</sup>

### Sleep staging

The PARADISEP&D9600 (USA) PSG monitoring and analysis system will be used to simultaneously monitor electroencephalogram (EEG), electrooculogram (EOG) and electromyogram (EMG). A large clinical dataset of PSG recordings will be used to train a hybrid convolutional neural network and recurrent neural network to learn effective and generalisable features for sleep stage scoring.<sup>39 40</sup> Then clinical data will be used to identify the deep learning algorithm. Sleep staging for both datasets will be performed by expert sleep technicians in non-overlapping 30s epochs according to standards by the American Academy of Sleep Medicine, as one of five stages: wake (W), non-REM stage 1 (N1), non-REM stage 2 (N2), non-REM stage 3 (N3) and REM.<sup>41</sup>

### Adverse events

During treatment and 4 weeks after treatment, a questionnaire will be administered to evaluate the various discomforts that may be caused by acupuncture: hang-over, addiction, tolerance, fatigue after waking, insomnia rebound, daytime alertness, cognitive function and behaviour ability.

### Patients and public involvement

Patients and the public are not involved in the design or conduct of the study or the outcome measures, and no attempt will be made to assess the burden of the intervention on the patients themselves. The results of this study will be disseminated to study participants via the website of our hospitals.

### Statistical analysis

All analyses will be performed on the intention-to-treat (ITT) population of participants who had at least one treatment. Missing data will be replaced according to the principle of the last observation carried forward. Data analyses will be performed using the SPSS V.25 (IBM) software. All available data will be analysed descriptively. For continuous data, the normality test will be applied at the beginning of the analysis. Results will be presented as means, SDs and 95% CIs for continuous data that conform to the normal distribution and medians, quartiles and ranges for rank data and continuous data that are not normally distributed. Discrete data will be presented as percentages.

We will first examine the descriptive data for sample characteristics at baseline, and independent samples t-tests will be used to compare groups for continuous variables, whereas  $\chi^2$  analysis will be used to compare groups for dichotomous variables. Second, we will perform two series of repeated-measures and univariate analyses of covariance (ANCOVA) models to examine treatment effects. We will use repeated-measures ANCOVAs to analyse the primary and secondary outcome measures (ie, PSQI, BDI, BAI, DBAS-16 and sleep staging scores) from pretreatment to post-treatment. If a significant effect is observed, we will conduct post hoc paired



samples t-tests to examine within-group changes in study outcomes. For all study outcomes, we will then perform univariate ANCOVAs to test for group differences in post-treatment values while controlling for relevant covariates. This process will be repeated to examine changes in study outcomes from pretreatment to postnatal follow-up.

When necessary, ITT analysis and sensitivity analysis will be used to assess the robustness of the conclusions of the entire clinical trial. To evaluate the consistency of the trial and explore the factors that affect efficacy or prognosis, subgroup analysis will be conducted to identify the population with better efficacy. Safety analysis will be used to assess the incidence of adverse events and related symptoms in patients with insomnia during treatment and follow-up.

### Limitations

Currently, CBT-I is recommended as a first-line treatment for insomnia, but it is limited in clinical practice especially in developing countries such as China.<sup>42–45</sup> As a complementary alternative therapy with a long history in China, acupuncture has been used as a clinical treatment for insomnia with fewer adverse effects and less permanent damage in previous studies.<sup>13 14 16</sup> In this study, we will focus on whether electroacupuncture combined with CBT-I could influence sleep quality and sleep architecture, but whether acupuncture therapy alone could influence sleep habits and correct cognition, also sleep architecture worth further research.

During the past decade, there have been various advances in automated sleep staging of PSGs data using the ability of deep learning methods to automatically extract features from data that are relevant to the classification, moreover, the performance of deep neural networks continues to improve as datasets become larger.<sup>46–50</sup> To analyse the effects of electroacupuncture combined with CBT-I on sleep architecture, deep learning will be used to analyse PSGs in various clinical settings in this study. But due to lack of acceptability among patients, some of the participants received placebo treatment will drop, which may make analyses no meaningful due to the small number of participants in each arm. Notwithstanding, we will be able to optimise the randomised design and statistical analysis to avoid systematic errors and minimise the bias.

### Ethics and dissemination

This trial has been approved by the institutional review boards and ethics committees of the First Affiliated Hospital of Sun Yat-sun University (2021763). The results will be disseminated through peer-reviewed journals. The results of this trial will be disseminated through peer-reviewed publications and conference abstracts or posters.

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**Contributors** WP and TH designed the trial protocol and drafted the manuscript. LL, JR and GW revised the manuscript. PY, XL and BJ will plan the data analysis. LC, YY, FM, GH and XZ will participate in participant recruitment. All authors discussed, read and revised the manuscript, and all approved the publication of this protocol.

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**Competing interests** None declared.

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**Patient consent for publication** Not applicable.

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