

Effects of shallow needling for chronic primary insomnia: A study protocol for a randomized controlled trial

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Abstract

Background: Primary insomnia (PI), commonly identified by difficulties in initiating and/or maintaining sleep, negatively impacts both physical and mental health and increases the risk of occupational and vehicular accidents. Previous researches have indicated that shallow needling, a form of acupuncture, may ameliorate symptoms of primary insomnia. Nevertheless, the scientific evidence regarding its efficacy in enhancing sleep quality remains limited.

Objective: This trial aims to assess the therapeutic efficacy of shallow needling in the treatment of chronic primary insomnia in adults.

Methods: A single-center, prospective, assessor-blinded, and randomized controlled clinical trial with two parallel arms will be conducted in the Affiliated People's Hospital of Fujian University of Traditional Chinese Medicine. A total of 124 participants with primary insomnia will be randomly divided into control group and treatment group in a ratio of 1:1 (n=?62 for each group). The control group will take eszopiclone orally at 1 mg once a day for 4 weeks. In addition to taking eszopiclone, the treatment group will receive shallow needling therapy once daily, five times a week, for 4 weeks. Data will be collected at three timeslots (pre, post, 4-weeks follow-up) and analyzed using SPSS 23.0. The primary outcome measure is Pittsburgh Sleep Quality Index (PSQI). Secondary outcome measures are Hamilton anxiety scale (HAMA), Insomnia Severity Index (ISI), Serum neurotransmitter detection (including the content of dopamine [DA], norepinephrine [NE], and melatonin [MT]), sleep parameters, and Magnetic Resonance Spectroscopy (MRS) of the thalamus.

Results: Subject recruitment is currently underway. The first participant was enrolled in August 2023, marking the official start of the experiment. As of the submission of this paper, a total of 120 subjects have participated in this clinical trial. The recruitment is expected to continue until August 2025, at which point the data processing and analysis will commence.

Conclusions: This study will evaluate the therapeutic effectiveness and safety of shallow needling in the treatment of chronic insomnia, so as to provide the necessary scientific basis for the clinical application and promotion of shallow needling. The findings of this study may provide a scientific and standardized treatment protocol for shallow needling in adults with chronic insomnia. Clinical Trial: ITMCTR2024000409. Registered on 30 August 2024, Version 1.0.

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Original Manuscript

Effects of shallow needling for chronic primary insomnia: A study protocol for a randomized controlled trial

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Abstract

Background: Primary insomnia (PI), commonly identified by difficulties in initiating and/or maintaining sleep, negatively impacts both physical and mental health and increases the risk of occupational and vehicular accidents. Previous researches have indicated that shallow needling, a form of acupuncture, may ameliorate symptoms of primary insomnia. Nevertheless, the scientific evidence regarding its efficacy in enhancing sleep quality remains limited.

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Discussions: This study will evaluate the therapeutic effectiveness and safety of shallow needling in the treatment of chronic insomnia, so as to provide the necessary scientific basis for the clinical application and promotion of shallow needling. The findings of this study may provide a scientific and standardized treatment protocol for shallow needling in adults with chronic insomnia.

Clinical trial registration: ITMCTR2024000409. Registered on 30 August 2024, Version 1.0.

Abbreviations: PI = Primary insomnia, PSQI = Pittsburgh Sleep Quality Index, HAMA = Hamilton anxiety scale, ISI = Insomnia Severity Index, DA = dopamine, NE = norepinephrine, MT = melatonin, MRS = Magnetic Resonance Spectroscopy, CBT = Cognitive Behavioral Therapy, RCT = randomized controlled trial, TST = total sleep time, SL = sleep latency, WASO = wake after sleep onset, SE = sleep efficiency, REM = rapid eye movement sleep phase, GABA = γ -aminobutyric acid,

Glx = glutamate/glutamine, NAA = N-acetylaspartate, Cho= choline-containing compounds, CRF = Case report form.

Keywords: shallow needling; chronic insomnia; acupuncture; study protocol; randomized controlled trial

Introduction

Insomnia is one of the most common sleep disorders globally, characterized by difficulty falling and staying asleep, early morning awakenings, and an inability to return to sleep[1]. It may occur secondary to psychiatric or organic disorders, the use of prescribed or illicit substances, alcohol consumption, or a combination of these factors. However, insomnia can also occur independently, known as primary insomnia (PI), which is driven by a psychophysiological hyperarousal process[2]. Previous studies have suggested that approximately 6% to 10% of adults meet the diagnostic criteria for insomnia[3], with PI accounting for an estimated 25%. Of note, many of these patients experience a chronic course[4]. Chronic insomnia has been associated with a wide range of adverse health outcomes, including headaches, dizziness, hypertension, and various cardiovascular and cerebrovascular diseases, which collectively undermine physical health, reduce quality of life, and pose significant risks to public safety. These effects result in substantial harm to both individuals and society[5,6]. Therefore, chronic primary insomnia has become a critical public health issue in contemporary society.

Sedative drugs and cognitive behavioral therapy (CBT) are the primary interventions for insomnia[7]. Although sedative drugs have a fast onset of action, the adverse effects for long-term use are notable, including persistent sleep difficulties, performance issues, memory disorders, driving accidents, and withdrawal syndrome[8]. In contrast, CBT is widely recognized as the first-line treatment for chronic insomnia by recognized organizations, including the American College of Physicians (ACP)[3], the American Academy of Sleep Medicine (AASM)[9], and the European Sleep Research Society (ESRS)[7]. Despite its effectiveness for insomnia, CBT is not commonly used due to the intensive labor required and high costs, which may lead to low patient compliance[10]. Given these limitations, it is crucial to seek additional safe and effective non-pharmacological treatments to optimize existing therapies for chronic insomnia.

As an important component of traditional non-drug therapy, acupuncture has long been used for the treatment of insomnia in China[11]. In recent years, a growing body of evidence-based researches have reported the effectiveness and feasibility of acupuncture therapy in improving sleep quality[12–15]. Acupuncture is thought to increase the quality of sleep by modulating the autonomic nervous system and regulating neurotransmitter levels, such as dopamine and melatonin, which play crucial roles in the sleep-wake cycle[16,17]. However, in clinical practice, the discomfort and pain associated with traditional acupuncture often cause significant distress and fear among patients, which limits its widespread acceptance. Therefore, the development of non-invasive and painless acupuncture techniques has become a key focus of research in this field. Researchers are continually exploring innovative methods to overcome these limitations and make acupuncture more accessible to patients.

Shallow needling, a special type of acupuncture, is derived from the "hammer needle" in the ancient system of nine needles. The National Famous Senior Traditional Chinese Medicine Experts, Wu Binghuang and Liang Dongfu, have inherited and innovated this therapy, developing it into a characteristic acupuncture method of Fujian Province[18]. In 2019, it was listed as part of the sixth batch of intangible cultural heritage projects in Fujian Province, and was selected as a characteristic traditional Chinese medicine technique by the National Administration of Traditional Chinese Medicine. Shallow needling is a non-invasive technique in which the rounded needle tip rests on the skin surface without penetrating it. Compared to conventional acupuncture needles, the needles used in shallow needling are designed with a thicker body, a longer handle to facilitate scraping with the fingernail, and a rounded tip that rests on the skin surface, avoiding penetration and minimizing discomfort (Figure 1). The technique involves applying a scraping motion with the fingernail on the needle handle at specific acupoints on the body surface to produce the needle sensation. This method

promotes the flow of meridian Qi and blood, regulate the internal balance of the body, and treats various diseases.

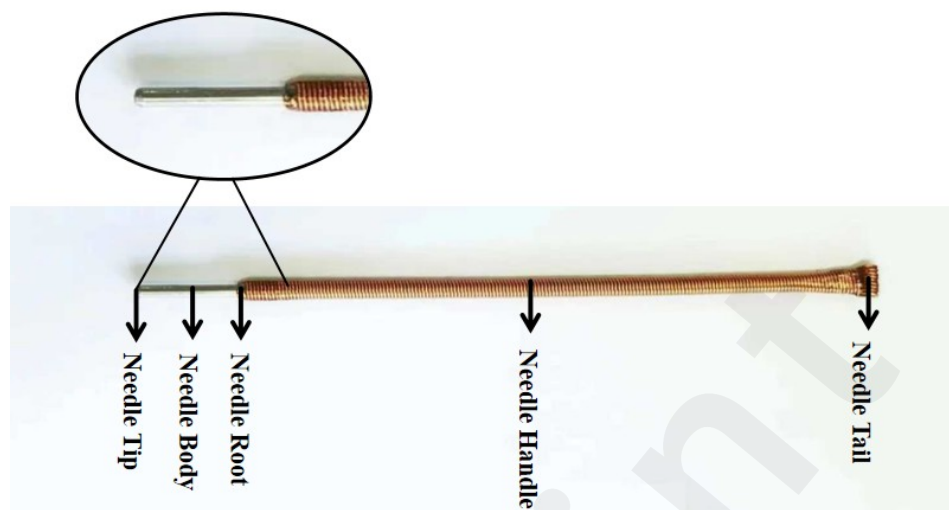


FIGURE 1: Structure of the shallow needling used in this study, illustrating key components, including the needle tip, body, root, handle, and tail.

Shallow needling retains the advantages of traditional acupuncture, including a wide range of indications, significant efficacy, and high safety profile. As a non-invasive and painless alternative, shallow needling is an attractive option for patients seeking less discomfort during treatment. Although shallow needling shows promising potential, its clinical efficacy in treating insomnia has not been thoroughly explored. A recent systematic review and meta-analysis[19] highlighted that shallow needling may offer a promising treatment option for insomnia. The analysis demonstrated that compared to non-shallow needling treatments, shallow needling demonstrates greater efficacy in reducing PSQI scores and improving clinical efficacy rates. However, due to the small sample sizes and the reliance on subjective outcome measures in most of the included studies, further research with larger sample sizes and rigorous study designs is highly needed to substantiate these promising findings. Additionally, the mechanisms underlying shallow acupuncture are not yet fully understood. Without a clear scientific foundation, it will be difficult to widely implement this technique in clinical practice.

Therefore, it is crucial to conduct randomized controlled trials (RCTs) with larger sample sizes and high-quality, well-designed treatment protocols to investigate the clinical effectiveness of shallow needling. This study aims to objectively evaluate the efficacy, and safety of shallow needling for chronic primary insomnia by assessing changes in sleep quality, anxiety levels, sleep architecture, serum neurotransmitter concentrations, and thalamic metabolite levels using Magnetic Resonance Spectroscopy (MRS). Findings of this study may provide valuable insights into the

neurophysiological mechanisms underlying shallow needling's effects on insomnia.

Methods

Research objectives

The purpose of this study is to evaluate the efficacy and safety of shallow needling in the treatment of chronic insomnia. The results of this study may provide a noninvasive and painless alternative therapy for patients with chronic insomnia.

Hypotheses

We hypothesize the following:

1. Compared with the control group, the symptoms of insomnia and anxiety in the treatment group were significantly relieved after treatment according to the scale evaluation. At the same time, according to the objective sleep outcome test results, the sleep treatment of the treatment group was further proved to be improved.
2. Compared with the control group, the levels of serum neurotransmitters and the levels of central neurotransmitters and metabolites in the treatment group were significantly improved, reflecting the better regulatory effect of shallow needling.

Study design

This study design is a prospective, randomized controlled trial with two parallel arms. The protocol received approval from the Ethics Committee of The Affiliated People's Hospital of Fujian University of Traditional Chinese Medicine (Ethics Approval Number: IRB 2023-014-02) and will be implemented at this institution. The trial is registered with the International Traditional Medicine Clinical Trial Registry under the number ITMCTR2024000409 (<http://itmctr.ccebtcn.org.cn/>). This protocol follows the guidelines of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT). We will compare the differences of shallow needling with pharmacotherapy on chronic primary insomnia in adults. The study procedure and details are presented in Figure 2 and Figure 3.

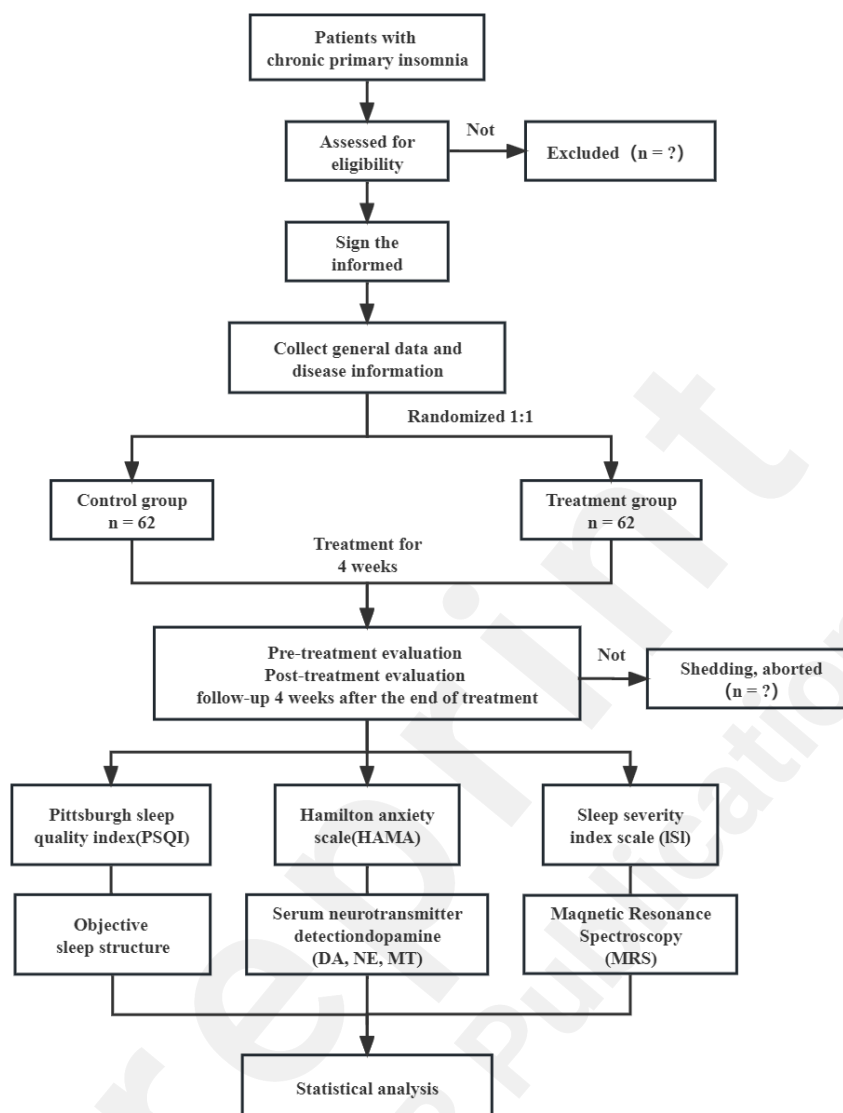


FIGURE 2: Flow diagram of the trial.

	STUDY PERIOD						
	Enrolment allocation		Intervention (weeks)				Follow-up
TIMEPOINT	-1 week	0 week	1 w	2 w	3 w	4 w	8 weeks
ENROLMENT:							
Eligibility screen	X						
Informed consent		X					
Randomization		X					
Allocation		X					
INTERVENTIONS:							
Taking eszopiclone orally			◆—————◆				
Taking eszopiclone orally and required shallow needling			◆—————◆				
ASSESSMENTS:							
PSQI		X				X	X
HAMA		X				X	X
ISI		X				X	X
Serum neurotransmitter detection		X				X	X
Objective sleep structure		X				X	
MRS of the thalamus		X				X	
SAFETY EVALUTION:							
Adverse events			◆—————◆				

Figure 3: Study schedule of enrolment, interventions, and assessments.

Participants

Sample size

According to relevant literature[20], the overall efficacy rate for the control group is reported to be 79.48%, while the treatment group is expected to have an efficacy rate of 98%. Assuming a significance level (α) of 0.05 and a power ($1-\beta$) of 0.9, the sample size was calculated using PASS 15.0 software. A minimum of 56 participants are initially required for each group. Considering a 10% dropout rate, we plan to recruit at least 62 participants per group. Therefore, a total of 124 participants are needed for current study.

Inclusion criteria

Patients meeting all of the following criteria will be enrolled in the study:

- (1) patients who met the diagnostic criteria;
- (2) insomnia patients aged 18 to 65 years;
- (3) PSQI score ranged from 7 to 15;

- (4) the duration of the disease ≥ 3 months;
- (5) no communication and cognitive impairment;
- (6) voluntary enrollment and signed informed consent.

Exclusion criteria

Patients meeting any of the following criteria will be excluded from the study:

- (1) secondary insomnia;
- (2) those who do not wish to undergo shallow needling therapy;
- (3) pregnant or lactating women, or those who intend to become pregnant;
- (4) combined with heart, liver, kidney, lung, brain and other serious organic diseases;
- (5) participants in other studies that influenced the results of this study.

Recruitment

We will recruit participants by posting advertisements on WeChat. Additionally, a series of educational lectures on shallow needling for chronic insomnia will be held at The Affiliated People's Hospital of Fujian University of Traditional Chinese Medicine to attract potential participants. All participants who meet the selection criteria will sign an informed consent form after understanding the purpose of the study and the program implementation process. Individuals' personal information will be collected and securely stored in a separate cabinet to ensure the confidentiality.

Procedures

Randomization and blinding

A research assistant will generate the randomization sequence using SPSS 23.0. The sequence numbers, group assignments, and random numbers will be printed on randomization cards and placed in sealed, opaque envelopes. Eligible participants will be randomly allocated to either the treatment group or the control group in a 1:1 ratio. Because of the specific nature of the shallow needling procedure, we could not blind the investigators and participants, but outcome assessors and statisticians would be unaware of the trial-group assignments.

Interventions

The control group

Subjects in the control group will take oral Eszopiclone (trade name: Itannin, manufactured by Chengdu Kanghong Pharmaceutical Group Co., Ltd., approval number: Sinopharm H20100074) at a

dose of 1 mg before bedtime daily, for 4 weeks.

The treatment group

In addition to Eszopiclone (same as the control group), participants will receive shallow needling therapy daily, five times a week, for 4 weeks.

The selected acupoints are Shangen (located at the intersection of the line connecting the inner canthi of both eyes and the midline of the nose), Zhenjing (located 0.3 cun above Yintang [GV29], with 1 cun being approximately the width of the patient's thumb at the knuckle), and Ezhong (located at the midpoint of the line connecting the hairline and Yintang). The locations of the acupoints are showed in FIGURE 4.

Before treatment, the participants are told to lie in a supine position in a quiet environment. The practitioner wraps a small piece of disinfected cotton around the tip of the needle and places it on the acupoint, applying light pressure without penetrating the skin. The practitioner uses the pad of the thumb to stabilize the needle handle, making sure the tip is perpendicular to the surface of the acupoint. The practitioner uses the edge of the middle fingernail to continuously scrape upward and downward along the needle handle, creating gentle and uniform vibrations. Each cycle of 81 scraping motions is one dose of stimulation, with three doses per acupoint.

The shallow needling will be performed by three licensed acupuncturists with at least 5 years of clinical experience in acupuncture. They will receive comprehensive training on the study procedures and shallow needling techniques before participating in this study.

In order to ensure the accuracy and reliability of the results of this trial, the use of other disease-related treatments was prohibited during the trial.

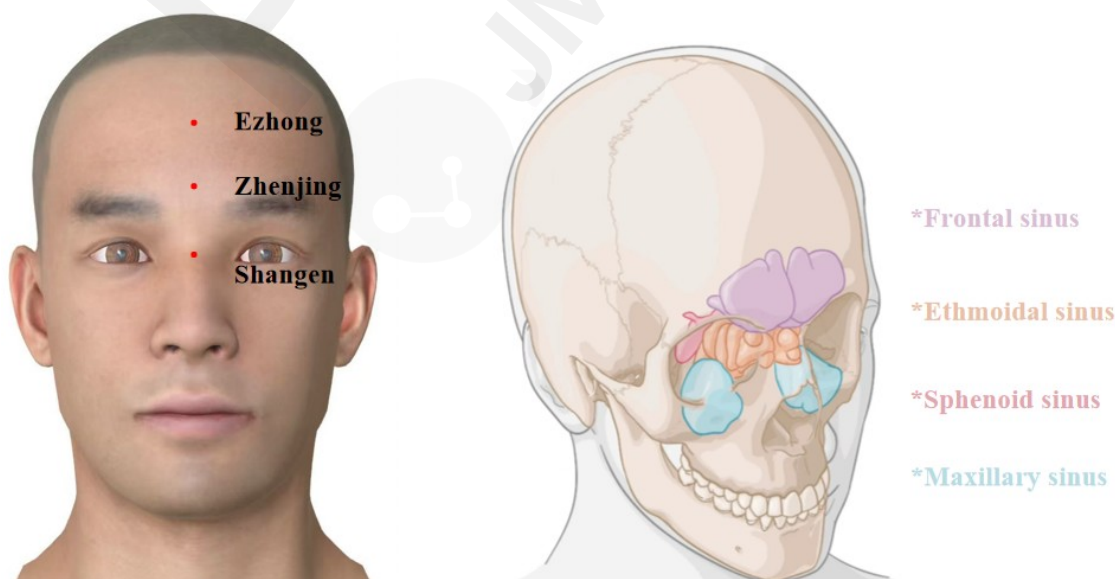


FIGURE 4: The anatomical locations of the acupoints.

Follow-up

The aim of the follow-up procedure is to assess the long-term effects of shallow needling for chronic primary insomnia. Follow-up assessments will be conducted after the 4 weeks intervention program. No further interventions will be provided during this period. Participants will obtain the same outcome measures as pre-intervention. Regular reminders will be given to ensure adherence, and any adverse events will be recorded and monitored by researchers. This follow-up procedure is essential for understanding the long-term effects of shallow needling.

Outcome measures

Primary outcome measures

Pittsburgh sleep quality index (PSQI)[21] is a questionnaire used to assess an individual's sleep quality, with good reliability and validity, indicated by a Cronbach's α coefficient of 0.83 and test-retest reliability of 0.85[22]. It consists of 7 components: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The total score ranges from 0 to 21. A global PSQI score greater than 7 indicates the presence of sleep disorders, with higher scores reflecting poorer sleep quality. PSQI will be assessed before treatment, after treatment, and 4 weeks post-treatment (follow-up).

Secondary outcome measures

Hamilton anxiety scale (HAMA)[23] is a scale that consists of 14 items with a scale ranging from 0 to 4. Higher scores indicate more severe anxiety. This scale is usually used to measure the levels of anxiety. The evaluation time points are the same as the primary outcome indicator.

Sleep severity index scale (ISI)[24] is a self-assessment scale used to measure an individual's experience of insomnia. It consists of seven items, each rated on a scale from 0 to 4. Higher scores indicate greater severity of insomnia. The total score ranges from 0 to 28, categorized as follows: 0-7 (no insomnia), 8-14 (mild insomnia), 15-21 (moderate insomnia), and 22-28 (severe insomnia). Assessment time points align with the primary outcome measure.

Objective sleep structure: Overnight sleep monitoring will be conducted using a polysomnography device (model: Alice 6 LDxN/LDxS, purchased from Respirationics). The parameters, including total sleep time (TST), sleep latency (SL), wake after sleep onset (WASO), sleep efficiency (SE), and the percentage of total sleep time (TST) spent in rapid eye movement (REM) and non-REM sleep stages 1, 2, and 3/4 (with stages 3 and 4 combined as deep sleep, reported as REM%, N1%, N2%, and N3%) were selected for outcome measurement. Participants

will undergo sleep monitoring from 19:00 to 07:00 on the day before treatment and the day after the completion of the treatment course in the hospital.

Serum neurotransmitter detection: Fasting blood samples (5 mL) will be collected from participants between 08:00 and 10:00. Blood samples will be centrifuged at 3000 rpm to separate the serum and subsequently stored in a laboratory freezer at -80°C. The concentrations of dopamine (DA), norepinephrine (NE), and melatonin (MT) will be measured using enzyme-linked immunosorbent assay (ELISA) kits, according to the manufacturer's instructions (Shanghai Enzyme-linked Biotechnology Co., Ltd). Measurements will be taken one day prior to treatment, one day after the completion of the treatment course, and at a 4-week follow-up.

Thalamic MRS: Scans will be performed with a 3.0T magnetic resonance scanner (Philips Ingenia CX 3.0T, Philips Healthcare, Amsterdam, Netherlands). Participants will be required to keep their eyes closed, remain at rest, but stay awake during scanning. The bilateral thalamus will be selected as the region of interest, and all scans will be performed by the same experienced radiologist. Imaging parameters: The s2D_PRESS_144 sequence will be used for data acquisition, with a total scan duration = 5 minutes and 52 seconds; the field - of - view (FOV) of the equipment: AP (anterior - posterior) diameter = 230 mm, RL (right - left) diameter = 192 mm; the size of the acquisition voxel = 10.0×10.1×15.0 mm; the echo time (TE) = 144 ms, the repetition time (TR) = 2000 ms; the acquisition matrix = 23×19, the slice thickness = 15 mm; the scan percentage = 100%.

After the acquisition of MRS data, post - processing will be executed using the MR Spectro View software installed on the ISP workstation. This post - processing will mainly involve tasks such as noise reduction, frequency calibration, and baseline correction. Subsequently, the processed data will be analyzed to measure the levels of γ - aminobutyric acid (GABA), glutamate/glutamine (Glx), N - acetylaspartate (NAA), and choline - containing compounds (Cho) in the thalamic region. The software will identify the characteristic peaks of these metabolites in the MRS spectra and calculate their relative concentrations based on the peak areas and predefined algorithms. MRS will be conducted before and 4 weeks after treatment to assess the changes in central neurotransmitter and thalamic metabolite levels.

Adverse event monitoring

Adverse events in this study will be closely monitored, with all details recorded in the CRFs to ensure that patients receive timely and appropriate management. Adverse events, including discomfort at the shallow needling site and drug-related reactions including nausea, vomiting, and dizziness will be documented. Any serious adverse events will be promptly reported to the ethics

committee to ensure participant safety.

Statistical analysis

In this study, data will be analyzed with SPSS 23.0 software. Continuous variables will be reported as mean and standard deviation, Categorical variables will be presented as frequencies or percentages. To compare continuous variables between the two groups, normality and homogeneity of variance will be initially evaluated. If these assumptions are satisfied, a t-test will be employed. Otherwise, a non-parametric rank-sum test will be utilized. Categorical variables will be analyzed using the Chi-square test or Fisher's exact test. *P* values of ≤ 0.05 will be considered statistically significant.

Data collection and management

Data will be collected by dedicated staff at the study center, and both the electronic medical record and Case report form (CRF) will be used to collect the data. In principle, missing values are not allowed in the report form, and in particular, important measures (the primary safety measure) must be clearly reported. The results measured in the test were zero and failed to measure, should be corresponding symbols, can not be vacant, so as to distinguish from missing values. If there are missing values, the original data should be searched first to determine whether the data is missing. If it is indeed missing, the data should be filled in. If the missing value is an important indicator related to safety, the subject should be informed to review immediately to ensure their safety. If the missing values affected the outcome, the case was excluded.

Quality control

All participants, including acupuncturists, evaluators, and statisticians, will be required to undergo training in order to ensure the studies' quality. And by formulating detailed and operable clinical trial specifications The intervention will be based on careful adherence to standard operating procedures.

All participants, including acupuncturists, evaluators and statisticians, need to be trained to ensure the consistency of relevant data collection and the quality of research through the development of detailed and operational clinical trial protocols. The intervention will be based on careful adherence to standard operating procedures, and the acupuncturists will perform standardized shallow needling procedures according to standard acupoint positioning. After the training, the assessment effects of the scale by outcome evaluators need to be checked for consistency, mainly

including: The same case was scored by independent examination by several outcome evaluators, and the same case was scored multiple times by one evaluator to ensure consistency of the scores.

The investigator will fill in all cases truthfully and carefully according to the design requirements of the "Case Report Form". Study medical records and case report forms are original records and cannot be altered.

Laboratory data in clinical trials should be documented and the original report or photocopy needs to be glued to the case report form.

In order to effectively improve the compliance of the subjects, during the stage of case screening and enrollment, it is necessary to maintain a patient and careful attitude, fully explain the purpose, process and significance of the study to the subjects, and ensure that the subjects clearly understand the relevant content. At the same time, the subjects were clearly informed to strictly follow the established requirements to ensure the smooth progress of the study and the accuracy of the data.

Results

Subject recruitment is currently underway. The first participant was enrolled in August 2023, marking the official start of the experiment. As of the submission of this paper, a total of 120 subjects have participated in this clinical trial. The recruitment is expected to continue until August 2025, at which point the data processing and analysis will commence.

Discussion

This study is a randomized controlled clinical trial aimed at evaluating the clinical efficacy of shallow needling in the treatment of chronic primary insomnia. The objectives include exploring a cost-effective, efficient, and safe standard therapy for chronic primary insomnia, as well as providing a scientific foundation for the clinical application and promotion of shallow needling therapy.

Through systematic data mining of extensive literature, we demonstrated that acupuncture points such as Shangen, Zhenjing, and Ezhong have been widely recognized for their efficacy in treating insomnia through shallow needling[25]. From the perspective of traditional Chinese medicine, these acupoints are located along the path of Du Meridian and correspond to the anatomical structures above the paranasal sinuses, where vibratory stimulation through shallow needling may induce resonance within the subcutaneous cavities. This resonance, combined with meridian conduction, is hypothesized to modulate brain function, contributing to the improvement of sleep. According to the records of Gong Degui[26], Professor Wu Binghuang frequently selected

these points, resulting in significant improvements in over 80 patients suffering from insomnia, with many experiencing sleep onset during the procedure. Our study will utilize these well-documented points to enhance therapeutic outcomes. Moreover, this trial avoids the use of skin-penetrating interventions, ensuring participant safety and enhancing both participant compliance and the feasibility of the study.

Earlier research has primarily focused on the short-term benefits of shallow needling. In contrast, our study design incorporates a four-week intervention phase followed by a four-week follow-up period. This design provides a comprehensive approach to investigating both immediate and long-term effects of shallow needling, offering insight into its therapeutic potential. Previous study[27] has demonstrated that shallow needling can induce changes in neurotransmitter levels and electrophysiological activity within the central nervous system, thereby influencing sleep quality. Our study incorporates sleep monitoring to provide an objective assessment of sleep architecture based on the above findings. Furthermore, we plan to investigate the potential neurophysiological mechanisms underlying shallow needling for insomnia by assessing the serum neurotransmitter levels and thalamic MRS.

The thalamus is a critical brain region involved in the regulation of sleep and wakefulness, functioning as a relay center for sensory and motor signals and playing a crucial role in sleep-wake transitions and sleep architecture[28]. Neuroimaging studies have demonstrated that alterations in thalamic activity are associated with sleep disorders, including insomnia[29]. Accumulating research has demonstrated that the occurrence of primary insomnia is closely linked to abnormal brain metabolites. Specifically, GABA and Glx maintain the balance between excitatory and inhibitory signals, are thought to be key players in sleep regulation. Of note, reduced GABA levels have been linked to hyperarousal in patients with insomnia, while abnormal Glx activity may contribute to disrupted sleep patterns[30]. MRS offers a non-invasive approach to quantify the concentrations of neurochemical substances within specific brain regions of living subjects[31], providing a valuable tool for exploring the neurophysiological effects of acupuncture. This study aims to observe whether shallow needling influences neurotransmitter and metabolites activity within the thalamus, potentially modulating sleep architecture and improving sleep quality through thalamic MRS.

While central regulatory mechanisms play a key role in sleep-wake control, these processes are also influenced by systemic neuroendocrine pathways that integrate signals across the body. Studies indicate that the circadian clock system located in the suprachiasmatic nucleus periodically stimulates both sleep-promoting and wake-promoting regions and inhibits or facilitates the cerebral cortex through the ascending inhibitory system or activation system, which causes either

wakefulness or sleep[32]. Neurotransmitters such as DA and NE are involved in these processes, promoting wakefulness or sleep through activation or inhibition of specific neural circuits[33]. MT is a hormone generated by the pineal gland in the brain that follows a circadian rhythm. It plays an important role in synchronizing the sleep-wake cycle and increasing sleep quality by signaling the commencement of sleep[34]. In this study, we will use ELISA to quantitatively analyze serum levels of DA, NE, and MT, which will provide insights into whether shallow needling influences sleep through systemic neurotransmitter regulations.

While our study comprehensively evaluates the efficacy of shallow needling for chronic primary insomnia, there are several limitations to consider. First, due to limited funding, we were unable to conduct a large-scale, multicenter trial, which may reduce the generalizability of our findings. However, our study offers a valuable foundation for understanding the efficacy of shallow needling, and we hope that more studies will build on these results to further refine the level of evidence. Second, with a 4-week follow-up period, there is a potential for selection and information bias due to participant attrition. To address this, we plan to implement retention strategies, including maintaining consistent communication with participants via social media and providing transportation subsidies to encourage adherence to follow-up. Lastly, given the unique nature of the intervention, it's difficult to implement blinding for the participants, which may introduce placebo effects. While we use objective measures, such as sleep architecture assessments and biochemical analyses, to mitigate this, the possibility of placebo effects should still be considered.

As far as we know, this is the first randomized controlled trial to objectively assess the efficacy of shallow needling for the treatment of insomnia and provide new insights into its neurophysiological mechanisms. The results of this study will establish a basis for the wider use of shallow needling in clinical practice and provide fresh evidence-based support for its application in treating insomnia.

Trial status

The trial is currently under recruitment.

Availability of data and materials

All data related to this study generated during the course of the study will be stored in the Affiliated People's Hospital of Fujian University of Traditional Chinese Medicine to ensure the safety and integrity of the data. For the data sets analyzed in this study, if there is a need for secondary analysis, you can apply to the corresponding author to obtain them, so as to provide

convenience for further research.

Ethics statement

This study has been approved by Ethics Committee of The Affiliated People's Hospital of Fujian University of Traditional Chinese Medicine (IRB 2023-014-02). All patients/participants provided written informed consent prior to their participation in this study.

Author contributions

WL, CW and BC conceived the experiment and participated in the study design. WL, MT and CW were responsible for drafting the manuscript. YJ and BC revised the original manuscript. BC and WL are the principal investigators of this study. YY and QH are the supervisors of this study. All authors read and approved the publication of this protocol.

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Conflict of interest

The authors state that they have no known competing financial interests.

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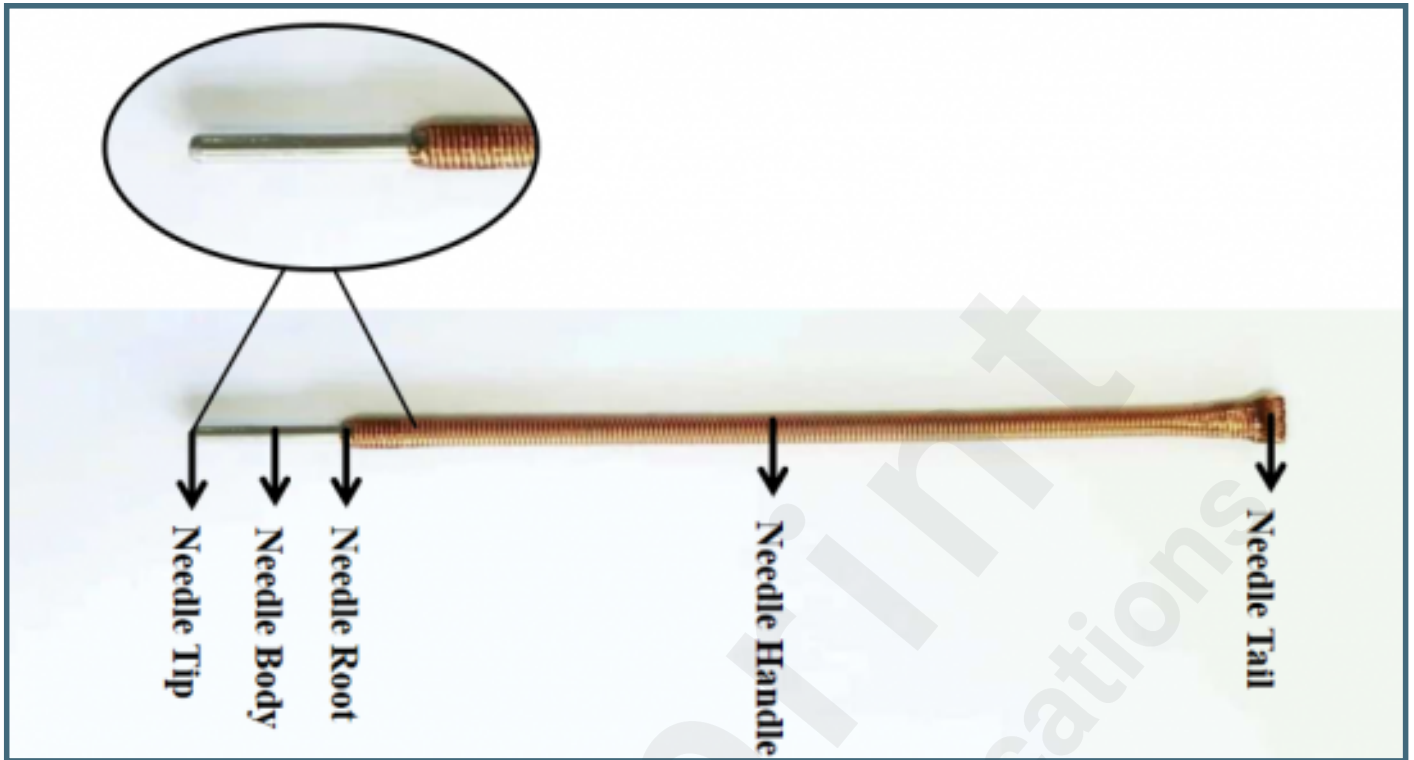
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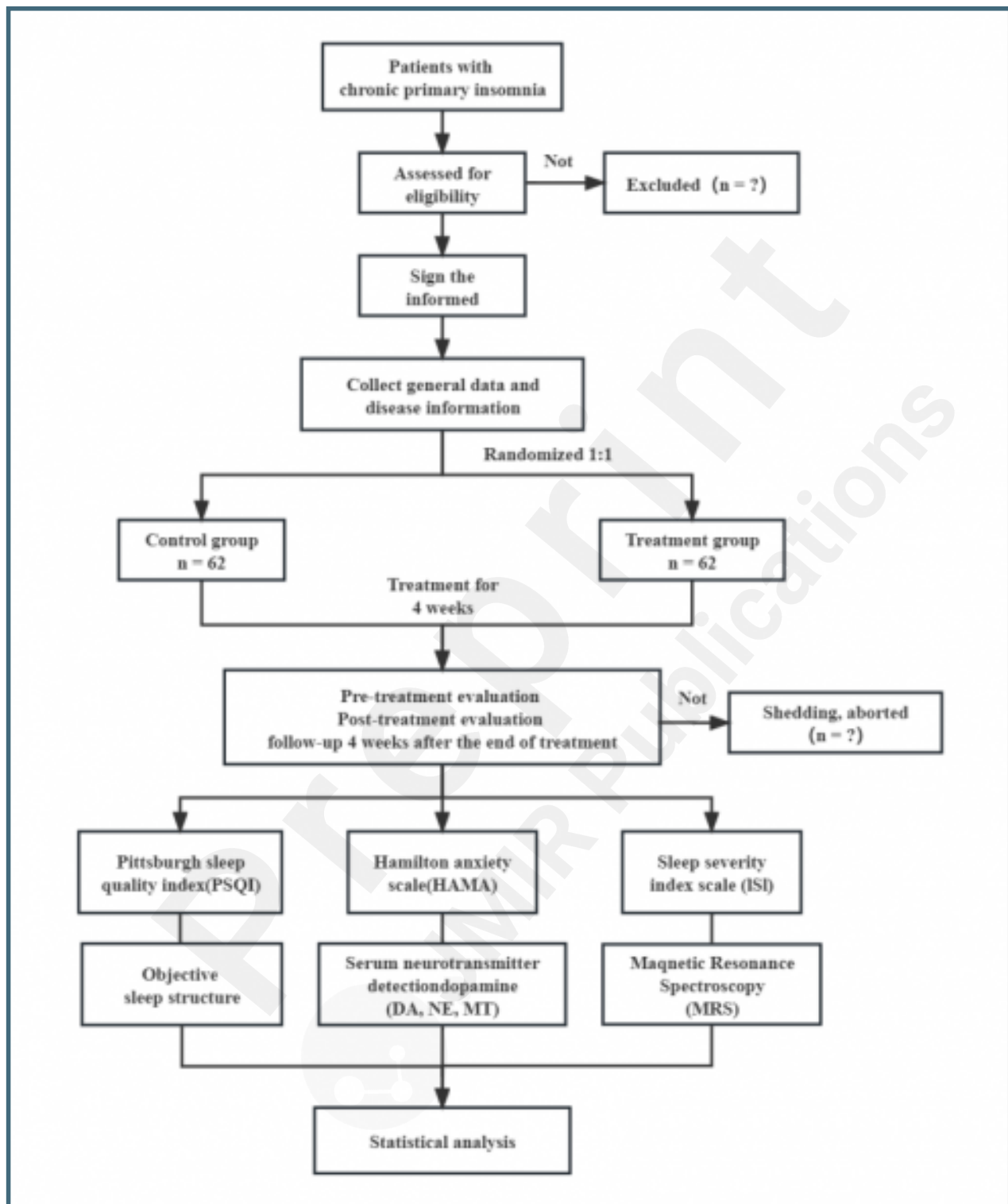
Supplementary Files

Figures

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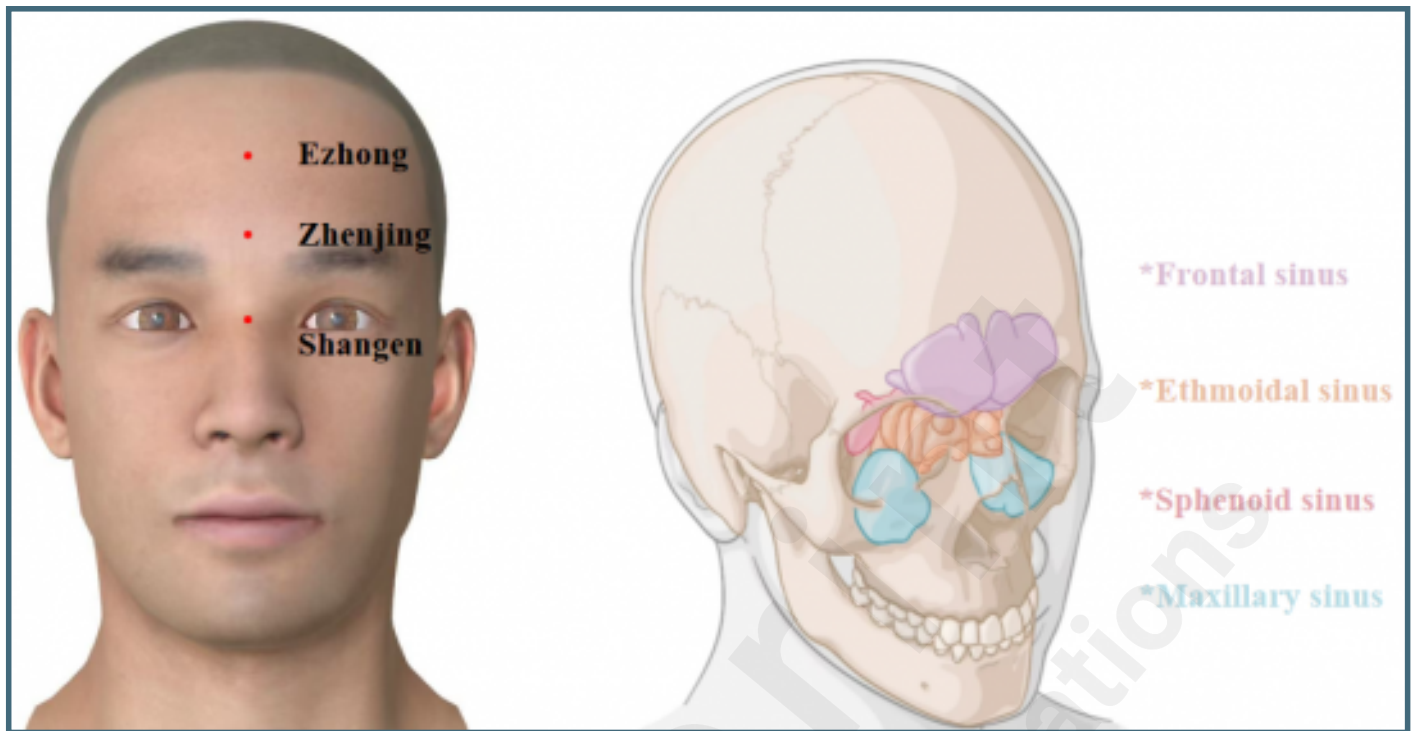
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	STUDY PERIOD						
	Enrolment allocation		Intervention (weeks)				Follow-up
TIMEPOINT	-1 week	0 week	1 w	2 w	3 w	4 w	8 weeks
ENROLMENT:							
Eligibility screen	X						
Informed consent		X					
Randomization		X					
Allocation		X					
INTERVENTIONS:							
Taking eszopiclone orally			←————→				
Taking eszopiclone orally and required shallow needling			←————→				
ASSESSMENTS:							
PSQI		X				X	X
HAMA		X				X	X
ISI		X				X	X
Serum neurotransmitter detection		X				X	X
Objective sleep structure		X				X	
MRS of the thalamus		X				X	
SAFETY EVALUATION:							
Adverse events			←————→				

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CONSORT (or other) checklists

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