Efficacy and safety of fire needle therapy for obstructive sleep apnea-hypopnea syndrome: study protocol for a single arm clinical trial

Linbo Shen
Beijing Hospital of Traditional Chinese Medicine, Capital Medical University
Hui Zeng
Beijing Hospital of Traditional Chinese Medicine, Capital Medical University
Yuqiang Song
Beijing Hospital of Traditional Chinese Medicine, Capital Medical University
Sanfeng Sun
Beijing Huairou District Hospital of Traditional Chinese Medicine
Jingfei Wang
Beijing Hospital of Traditional Chinese Medicine, Capital Medical University
Jingqing Sun
Beijing Hospital of Traditional Chinese Medicine, Capital Medical University
Yali Wen
Beijing Hospital of Traditional Chinese Medicine, Capital Medical University
Yuzhuo Zhang
Beijing Hospital of Traditional Chinese Medicine, Capital Medical University
Yuanbo Fu (fuyuanbosir@126.com)
Beijing Hospital of Traditional Chinese Medicine, Capital Medical University

Study protocol

Keywords: single arm clinical trial, OSAHS, fire needle, acupuncture, protocol

Posted Date: February 1st, 2023

DOI: https://doi.org/10.21203/rs.3.rs-2274030/v1

Abstract

Background

Obstructive sleep apnea hypopnea syndrome (OSAHS) is a sleep disorder characterized by repeated apnea and hypopnea while you're asleep, and the prevalence rate increases annually. Previous research revealed that the fire needle therapy for OSAHS good clinical efficacy but lacked proof from clinical trials. Therefore, we designed this single-arm clinical trial protocol to investigate the effectiveness and safety of treating OSAHS using fire needle therapy.

Methods/design:

166 adult subjects with mild to moderate OSAHS, ranging in age from 18 to 70, will be included in this study. All subjects will receive fire needle therapy twice a week for 4 weeks and follow-up for 12 months. The following points will include outcome assessment: (1) baseline;(2) 4 weeks following treatment's start;(3) 3 months following treatment's start; (4) 12 months following treatment's start. The primary outcome of the trial is the AHI index, and the secondary outcomes include oxygen desaturation index(ODI), lowest nocturnal oxygen saturation (LSpO2), percentage of SaO2 < 90% in total sleep time (TS90%), apnea index (AI), hypopnea index (HI), subjective symptoms (by ESS score, TCM syndrome score). Safety assessments include vital sign monitoring, routine blood tests, routine urine tests, blood biochemistry, the skin Reaction Scale, the modified Vancouver scar score, and adverse events.

Discussion

This single-arm clinical registry study will provide evidence-based medical evidence for the efficacy and safety of fire needle therapy in OSAHS.

Trail registration:

Chinese Clinical Trial Registry, ChiCTR2100042309. Registered on January 7, 2021.

1. Introduction

Backgroud and rationale

Obstructive sleep apnea hypopnea syndrome (OSAHS) is a common sleep disorder characterized by recurrent apnea and hypopnea during sleep. Prevalence of the disease has been increasing in recent years, which attract more and more attention from the public and become an important public health problem[1]. In addition to being a risk factor for stroke, hypertension, diabetes, heart failure and other

diseases, OASHS also causes abnormal behavior and cognitive decline, furthermore it is also an important cause of road traffic accidents and nocturnal sudden death[2].

The prevalence of OSAHS ranges 9%-38% in different regions, and it is estimated about 11% in Chinese adults[3]. The prevalence is higher in men. Considering that many patients with symptoms do not seek diagnosis and treatment, the actual prevalence may be higher. Chamara V. Senaratna reported that[4] 93% of women and 82% of men with moderate or severe OSAHS patients have not been clinically diagnosed. The possible reasons for patients' delay in seeking medical treatment include[5]: insufficient understanding of the disease, resistance to treatment and concern about prognosis, requirements of monitoring conditions and time limit of patients, and personnel knowledge and equipment limitation of primary medical units.

The key pathophysiological feature of adult OSAHS is repeated upper airway stenosis. The pathological mechanism includes four aspects: 1) low reactivity of pharynx muscle, 2) instability of respiratory center, 3) low arousal threshold and 4) anatomic factors, which often interact in clinical practice[6]. Repeated nighttime respiratory tract obstruction causes chronic intermittent hypoxia and carbon dioxide retention[7], resulting in hypoxemia and hypercapnia, and then release a variety of tissue factors, resulting in endothelial dysfunction, abnormal blood flow, abnormal coagulation state and other phenomena, resulting in serious cardiovascular and cerebrovascular diseases such as stroke, heart failure, atrial fibrillation[8]. In addition, the cerebral cortex repeatedly awaked at night disrupt the normal sleep rhythm, which could lead to series of adverse impacts including loss of concentration, depression, irritability, even memory or severe cognitive decline[9,10].

Currently, CPAP therapy is the first recommended treatment for OSAHS, especially for the patients at moderate and severe level. However, its physical side effects (such as noise, skin irritation, and claustrophobia), strict requirement of using time (at least 4 hours at night) and high expense troubled patients that 46-83% of them reported unable to adhere to treatment. The low patient compliance hardly achieves considerable sustained effectiveness, which have been supported by a study published on *Chinese Acupuncture & Moxibustion.*

In recent years, acupuncture therapy has drawn attention from the scholars in this field, and many clinical trials have verified that dry needle acupuncture can significantly improve the symptoms and PSG values of OSAHS patients. Fire needle therapy is a kind of acupuncture and moxibustion treatment with a special needle, which is heated and burned red and pierced into the acupoint or the affected part of the human body to get rid of diseases. Fire needle therapy has been an important part of Chinese acupuncture therapy since ancient times and has been widely used in acupuncture departments of many Chinese traditional medicine hospitals. Compared with ordinary dry acupuncture, fire needle has a stronger warming effect. From the perspective of TCM, the pathogenesis of OSAHS could be summarized as internal obstruction of phlegm and dampness, Qi stagnation and blood stasis; meanwhile, fire needle therapy plays a role in dispersing cold, removing dampness, dissolving phlegm and regulating Qi and

blood. Based on this theory, we designed a single arm clinical trial to determine the efficacy and safety of fire needle therapy in OSAHS.

Objectives

We intend to evaluate the efficacy and safety of fire needle therapy of OSAHS by using the single-arm clinical trial in this study. The purpose of this trial is to provide a feasible and convenient alternative treatment for patients who are intolerant and unwilling to receive CPAP.

2. Methods/design

Trial design

This study will be a single center and single arm prospective clinical trial. The clinical study coordinator will explain the purpose and procedure of this study to potential participants. The detailed process is shown in the flowchart Figure 1.

Study setting

The single arm clinical trial will be conducted at The Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University, and all participants who meet the inclusion criteria will receive fire needle therapy. Recruitment information will be posted on the hospital's official website.

This protocol has been approved by the Medical Ethics Committee of the hospital (Approval No. 2021BL02-056-02) and registered in the Chinese Clinical Trial Registry (www.chictr.org.cn) with the registration id ChiCTR2100042309.

Eligibility criteria

All participants will be judged by TCM physicians. Participants who meet the inclusion criteria and do not meet the exclusion criteria will be considered.

Diagnostic criteria

According to the Diagnosis and Treatment Guidelines for Obstructive Sleep Apnea Hypopnea Syndrome (Primary Edition) (2015)[14], the diagnostic criteria are mainly based on medical history, physical signs and portable monitoring (PM) or PSG monitoring results. OSAHS can be diagnosed if it meets either of the following conditions: Participants had typical nocturnal sleep snoring with apnea, daytime sleepiness (ESS score ≥9) and AHI > 5 times /h. (2) No significant daytime sleepiness (ESS score < 9), but AHI≥10 times /h. AHI≥5 times /h, with more than one underlying diseases including cognitive impairment, hypertension, coronary heart disease, cerebrovascular disease, diabetes and insomnia.

OSAHS can be classified into mild, moderate and severe level according to the AHI and the lowest SpO2 at night, of which the AHI is the main criterion and the other is for reference:

Mild: AHI:5-15 times /h, LSpO2 85%-90%;

Moderate: AHI: 16-30 times /h, LSpO2 80%-84%;

Severe: AHI: > 30 times /h, LSpO2 < 80%.

Inclusion criteria

The inclusion criteria for the study are as follows:

(1) Patients diagnosed with mild and medium OSAHS (an apnea index of 5-30 events per hour according to PSG).

(2) Patients never used respirator or didn't wear it within three months before study initiation.

(3) Patients aged 18-70 years

(4) Patients who are willing to take participation in need to sign the relevant informed consent form.

(5) Patients who can cooperate the treatment and adhere to the follow-up.

Exclusion criteria

Patients will be excluded from the trial if:

(1) Patient has severe structural deformities of upper airway, including but not limited to, enlarged tonsils, long tongue, fat tongue and glossoptosis.

(2) Patients are diagnosed with central sleep apnea.

(3) Patients who have concurrent systemic diseases such as cardiovascular, cerebrovascular hepatic, renal or hemopoietic system.

(4) Patients during pregnancy or lactation.

(5) Patients who are severely afraid of needles or are allergic to metals or have scars after being unable to receive fire needle treatment.

(6) Patients who are undergoing other clinical trials for which treatment may affect the efficacy of this study.

Criterion for trial suspension, patient rejection, and patient withdrawal are also set as follow

(1) Serious adverse events or complications have developed during the trial.

(2) Participants cannot adhere to treatment or withdrawal at the individual's discretion.

(3) People who participate in another trial without permission.

(4) Failed to complete at least 4 prescribed treatments due to patient's personal reasons.

Single-arm clinical trial with objective performance goal

As a non-drug therapy of traditional Chinese medicine, fire needle therapy is characterized by the use of tools or special movements, which makes it difficult to adopt double-blind in clinical trials. Secondly, parallel RCT is difficult to meet patients' expectations of therapeutic effects and a large number of patients in the control group may fall off or withdraw from the trial. The researchers may also have problems on selecting the therapeutic measurements[15]. Considering the benefit for patients, we chose a single-arm clinical trial that is more feasible in the real world to evaluate the efficacy and safety of fire needle therapy.

In the single-arm clinical trial, only the experimental group would be set up in the trial process. Patients who meet the inclusion criteria are sequentially included. We will perform the fire needle therapy and evaluate its efficacy, and then compare the outcomes with PG (performance goal). The key point of this method is the selection of outcome indicators. Relatively objective and repeatable indicators should be used as the main outcome indicators. Therefore, objective values such as AHI and ODI indexes measured by PSG(polysomnography) will be selected as the main outcome indicators. Another key point is the determination of PG. OPG (Objective Performance Goal) will be used as a comparison for verifying the efficacy of fire needle therapy. According to han Mei et al, the efficacy of CPAP, the standard treatment recommended by the guidelines, will be used as the contrast. The results are derived from authoritative meta-analysis of CPAP clinical studies. The objective and repeatable indicators, such as AHI and ODI indexes measured by PSG (polysomnography), are used as main outcome indicators. Meanwhile, the changing of OPG will be adopted to verifying the efficacy of fire needle therapy. The counterpart is the efficacy of CPAP, the standard treatment recommended by the guidelines. The results are derived from authoritative meta-analysis of CPAP clinical studies.

Randomization and masking

This single-arm clinical trial doesn’t involve randomization.

Blinding

Because of the particularity of the fire needle therapy, it is difficult to blind patients. Meanwhile, it is unnecessary to blind doctors in a single-arm trial. Blinding will be adopted in the stage of collection and efficacy evaluation to separate the researchers, outcomes assessors and data analysts. All statistical analysts and outcome evaluators will not be informed that the method of this trail.

Sample size

According to relevant literature, the effective rate of continuous positive airway pressure (CPAP) treatment and dry needle acupuncture is 53.6% and 67% respectively. In this study, it is expected the effective rate could reach 55%, which is higher than the CPAP treatment, so it can be recognized that fire needle therapy is effective in improving OSAHS. According to previous literature, Tang et al. [16]introduced a calculation method of sample size of single-arm trial performance goal method in non-drug TCM therapy. The sample size of this study is as follow, with AHI as the main outcome indicator.

$$n = \frac{[Z_{1-\alpha}\sqrt{\pi_0(1-\pi_0)} + Z_{1-\beta}\sqrt{\pi_1(1-\pi_1)}]^2}{(\pi_1-\pi_0)^2}$$

The Sample size (n=133) is calculated by SPSS. A total of 166 subjects will be required for this study, considering a dropout rate of 20%.

3. Intervention

Timeline

Participants will receive a series of medical examinations, including PSG examination, Epworth Sleepiness scale, TCM syndrome score and PSQI scale, to confirm the diagnosis of OSAHS. Subjects meeting the inclusion criteria will receive clinical intervention with fire needle acupuncture twice a week for 4 weeks, with treatment time on Monday and Friday afternoons each week (3-4 days between the two treatments). The results assessment will take at day 0, week 4, month 3, and month 12 after enrollment. Details are shown in Table 1.

Table 1.

Project	Dressing by screening	Leading-in	Stage of therapy	Follow-up period	
The order of medical treatment	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
time	-3~0 Days	0	4 weeks	12 Weeks	48 Weeks
Collect basic information					
Inclusion criteria and exclusion criteria	√	√			
The subjects were screened	√				
Informed consent form was signed	√	-	-	-	-
Fill in the population information	√	√			
vital sign	√	√			
Past history / treatment history	√	√			
Combined with diseases and treatment	√	√			
Effectiveness observation					
Sleep breathing monitoring(PSG/PM)	√		√		
Epworth Sleepiness Scale (ESS)	√	√	√	√	√
Pittsburgh Sleep Quality Index scale (PSQI)	√	√	√	√	√
Traditional Chinese medicine syndrome points	√	√	√	√	√
Evaluation of treatment expectations		√			
Evaluation of patient treatment satisfaction			√		√
Security observation					
Intravenous blood sampling (blood routine, cardiac, liver and renal function), electrocardiogram	√		√		
The Vancouver Scar Rating Scale			√		
Adverse events / Serious adverse events			√	√	√
Other work					
Test completion			√		√
Evaluation of compliance			√	√	√
The Auditor reviews the cases	**The inspectors set up by the project undertaking unit shall regularly supervise and review them**				

The inspector reviews the case	**The project quality supervision committee has set up inspectors to review all CRF**

PSG(Polysomnography) /PM(portable monitoring)

Overnight PSG monitoring is the standard method for diagnosing OSAHS, which includes electroencephalogram (EEG), electrooculogram (EOG), mandibular electromyogram (EMG), electrocardiogram (ECG), oral-nasal airflow, chest and abdominal respiratory movement, arterial oxygen saturation, body position, snoring and electromyogram of tibialis anterior muscle. Generally, this test required to sleep for at least 7 hours throughout the night. With the development of technology, portable monitoring (PM), known as Out of Center Sleep Testing (OCTS), has been utilized in recent years, which can record and analyze multiple sleep physiological data, such as oral-nasal airflow, arterial oxygen saturation, and is considered simple and practical.

Intervention description

Patients will receive fire needle therapy twice a week for 4 weeks. Selection of the acupuncture points: Baihui (GV20), Lianquan (CV23), Zhaohai (KI6), Lieque (LU7), Fenglong (ST40), Sanyinjiao (SP6). A schematic diagram of acupuncture points is shown in Figure 2.

Fire needle operation

The participants will fully expose the puncture sites. After located the acupoints, the operator will routinely disinfect his\her hands and the area around the acupuncture points on the participants. The next step, the operator will use a special needle made of manganese-ungsten alloy measuring 0.5×40 mm, ignite the spirit lamp or 95% alcohol cotton ball. The operator will burn the body of special needle in outer flame to disinfect it. Until about 12~13mm long area from the needle tip turns bright red, the operator will insert the needle into every acupoints 2~8mm rapidly, and quickly pull out the needle, rubbing the needle hole with a sterile dry cotton ball in order to prevent bleeding or infection.The fire needle is shown in the Figure 3 and Figure 4.

4. Outcomes

Primary outcome

The changing of mean in Apnea Hyponea Index(AHI) from the beginning to the end of treatment measured by PSG or PM will be the primary outcome. All subjects will be monitored by PSG or PM in a hospital ward or at their own home. To ensure consistency of measurements, the subjects are required to use the same type of monitoring before and after treatment.

Secondary outcomes

The secondary outcomes consist of the Epworth Sleepiness Scale(ESS), TCM syndrome integral, as well as ODI, LSpO2, TS90%, AI, HI assessed by PSG or PM.

(1) ESS

ESS, designed by Epworth Hospital in Melbourne, Australia, is a very simple questionnaire for patients to self-assess their daytime sleepiness. It sets eight hypothetical scenarios and the patient will evaluate the likelihood of nodding or falling asleep in these scenes. . Questions are graded on a scale of 0 to 3. Participants will complete the questionnaire without others' help to ensure the reliability. The score of 9 is a cut-off value, which means ESS 9 can be diagnosed in combination with other results.

(2) TCM syndrome integral

TCM syndrome integral is a subjective symptoms questionnaire. It includes the following symptoms: snoring, suppress wake, sleep quality, mental state, tiredness, lethargy, heavy limbs, nocturia, dry mouth, bitter mouth.

(3) Numeric value of PSG or PM

ODI: oxygen desaturation index.

LSpO2 lowest oxyhemoglobin saturation overnight.

TS90%:percentage of blood oxygen saturation 90% of total monitoring time.

AI: apnea index.

HI: hypopnea index.

ODI and TS90% reflect the hypoxia of patients during sleep over all night, while LSaO2 can better predict the occurrence of cardiovascular and cerebrovascular diseases in patients. The combination of these three indicators will help doctors accurately estimate the degree of hypoxia in patients and predict the development or prognosis of the disease.

(4) PSQI

PSQI (Pittsburgh sleep quality index scale) will be used to assess participants' sleep quality.PSQI is composed of 19 self-assessment and 5 other evaluation items, of which the 19th self-evaluation item and 5 other evaluation items do not participate in scoring. The other 18 items are composed of 7 components. Each component is scored according to 0~3 grade. The cumulative score of each component is the total PSQI score and the higher the score is, the worse the sleep quality is. It will take 5~10 minutes for participants to complete the PSQI questionnaires.

Safety

Safety assessments include participants' general health conditions (including vital signs, routine blood tests, blood biochemistry, routine urine tests, electrocardiograms), adverse events, and specific reactions related to the fire needle (e.g. skin reactions, scarring, burns). Vital signs will be recorded during each treatment. Routine blood tests, routine urine tests, blood biochemical tests will be performed at baseline and 4 weeks after treatment. Record the occurrence, treatment and results of adverse events in detail. The skin Reaction Scale and the Modified Vancouver Scar Scale (mVSS) will be used to evaluate the safety of fireneedle treatment.

5. Data Collect And Management

Data entry and extraction

A standardized Case Report Form (CRF) will be established for each enrolled participant to record the participant's general information, course of disease, history of present disease, past history and drug use. AHI, ODI, longest suspension time, average blood oxygen saturation during sleep, minimum blood oxygen saturation during sleep, percentage of blood oxygen saturation < 90% in total sleep time, ESS, PSQI, TCM syndrome score and other information will be recorded in detail. The completed CRF data will be entered into the computer system in duplicate by two trained physicians, and the data will be checked by a research coordinator. At the end of the study, statisticians will be able to download electronic data through the system for analysis.

Statistical Methods

Quantitative data such as AHI, ODI, longest suspension time, average oxygen saturation during sleep, minimum oxygen saturation during sleep, percentage of oxygen saturation < 90% in total sleep time, ESS score, PSQI score, TCM syndrome score before and after treatment will be described by mean ± standard deviation (m±s). If the normal distribution is in line with homogeneity of variance, t test will be used. The Satterthwaite method will be used to correct the t test for inconsistent variances. Wilcoxon rank sum test will be used to describe the non-normal distribution and median (quartile) [M (P25, P75)] also will be used.

All the statistical tests were conducted by bilateral test, and the hypothesis test level was set as 0.05 to calculate the corresponding P-value of the statistic. $P < 0.05$ was considered as significant difference and statistically significant.

Statistical analysis method of single target value method

In the statistical analysis of performance goal method (PG), the confidence interval method is mainly used for statistical inference, and the unilateral confidence interval of the main evaluation index is calculated. When the sample size is large, the confidence interval can be estimated by using the principle that the sample rate P approximates the normal distribution. When the sample size is small, the binomial distribution can be used to estimate the confidence interval. For the results of a single group of

experiments, the lower limit of the unilateral confidence interval of the outcome indicators should be higher than PG if the high optimal index is used, and the upper limit of the unilateral confidence interval of the outcome indicators should be lower than PG if the low optimal index is used, then the level of PG can be considered to be reached.

PG selection [15] : CPAP is currently recognized as the preferred therapy for the treatment of OSAHS. The target value was determined by referring to the Clinical Practice Guidelines for Positive Airway Pressure in the Treatment of Adult Obstructive Sleep Apnea [11] issued by the American Academy of Sleep Medicine in 2019. The effective rate of CPAP in the treatment of OSAHS was 53.6%.

In this study, the sample size n=166 (n>50), the interval estimation method of large sample rate should be used. In this study, AHI was selected as the primary endpoint index, and the lower limit of unilateral confidence interval calculated by AHI was required to be higher than PG, so it was considered that the effective rate of fire needle therapy reached PG.

Quality control and assurance system

The project leader will supervise and inspect the whole process of the study, confirm the authenticity, accuracy and completeness of all the records and reports of the research data and the case report forms, and ensure that they are consistent with the original data.

6. Discussion

In the past, obstructive sleep apnea was often regarded as a disease of otorhinolaryngology or respiratory system. In recent years, with the in-depth study of its pathological mechanism, it found that neuromodulation is also closely related to this disease. In the course of clinical practice, we found that acupuncture therapy has obvious effect on OSAHS, which is helpful in reducing snoring, reducing the time and frequency of apnea, alleviating daytime drowsiness and improving sleep efficiency. Chao Yuanfang, a physician of TCM in Yuan Dynasty, put forward that the core pathogenesis of OSAHS is the loss of Spleen health. Its dysfunction leads to the endogenesis of phlegm and dampness, which block the circulation of Qi and Blood. finally, the integration of phlegm and blood stasis becomes the main pathological products of OSAHS. Fire needle therapy has been an important part of Chinese acupuncture therapy since ancient times. It also has the characteristics of simple cheap and safe examination of ordinary acupuncture. In the theory of Traditional Chinese medicine, its warm and hot characteristics are beneficial to dampness, phlegm l and blood stasis elimination. At the same time, fire needle will introduce warm heat into the human body, which can stimulate Qi and Yang, and enhance the patient's defense against pathogenic factors. However, current studies on acupuncture treatment of OSAHS mostly focus on the verification of acupuncture's improvement of symptoms and indicators (such as AHI, ODI, blood oxygen, sleep, etc.). The way how acupuncture affects the development of the disease remains unknown, and its mechanism at the cellular and molecular levels needs to be studied.

In previous clinical studies on acupuncture treatment of OSAHS, the severity of OSAHS is rarely graded, which directly affects the accuracy of the evaluation of acupuncture efficacy. In this study, the team will include patients with mild to moderate OSAHS to better explain the beneficiary population of fire acupuncture.

The key technologies of this study are the needles, the selected acupoints, operation techniques, needle retention time and treatment course of fire needles which will be uniformly trained and standardized.

There are certain limitations in this study. As a single-arm trial method, there is no control group. The efficiency will be compared with standard therapy. To ensure the ethics we will collect safety indicators including blood routine, urine routine, liver and kidney function, and electrocardiogram. After the trial, the patients will also receive the Vancouver scar score and skin reaction score to evaluate the safety of the fire needle treatment, so as to ensure that the patients will not be harmed during the treatment.

In recent years, there have been some clinical studies on dry needle therapy for OSAHS. As far as we know, there is no clinical study on fire needle therapy for OSAHS at present. The results of this study will enrich OSAHS treatment approaches, provide valuable evidence on the merits and long-term efficacy of different treatments, and help promote the multidisciplinary treatment of OSAHS.

Abbreviations

OSAHS: obstructive sleep apnea hypopnea syndrome;

CPAP: continuous positive airway pressure;

PSG: polysomnography;

PM: portable monitoring;

AHI: apnea hyponea index;

ESS: Epworth sleepiness scale;

PSQI: Pittsburgh sleep quality index scale;

PG: performance goal;

OPG: objective performance goal;

EEG: electroencephalogram;

EOG: electrooculogram;

EMG: electromyogram;

ECG: electrocardiogram;

OCTS: out of center sleep testing;

TCM: traditional Chinese medicine

Declarations

Acknowledgements

We are very grateful for the supporting of Beijing Hospital of Traditional Chinese Medicine in this study. We also thank all participants for their trust.

Trial status

The study was registered in the Chinese Clinical Trial Registry in Jan 2021. Obtaining ethical approval in Jul. 2021.Recruitment began in Dec 2021 and is expected to end in Jun 2023. It is expected that 166 subjects will be recruited.

Funding

Key Medical Specialty Development Program of Beijing Hospital Administration Center: Rehabilitation of Integrated Chinese and Western Medicine: Key Medical specialty Approval Number: ZYLX202140; Beijing Municipal Science and Technology Commission_Capital Clinical Characteristic Diagnosis and Treatment Technology Research and Transformation Application: Z221100007422078.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Consent for publication

Not applicable.

Authors' contributions

YBF conceived the whole study, completed the ethical approval, LBS HZ assisted in the ethical review and drafted the manuscript, LBS, HZ and YQS participated in the recruitment of subjects, SFS, YZZ, JFW participated in follow-up and statistical analysis. YBF, JQS and YLW were treated with acupuncture. All participants have read the manuscript.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

Ethics approval and consent to participate

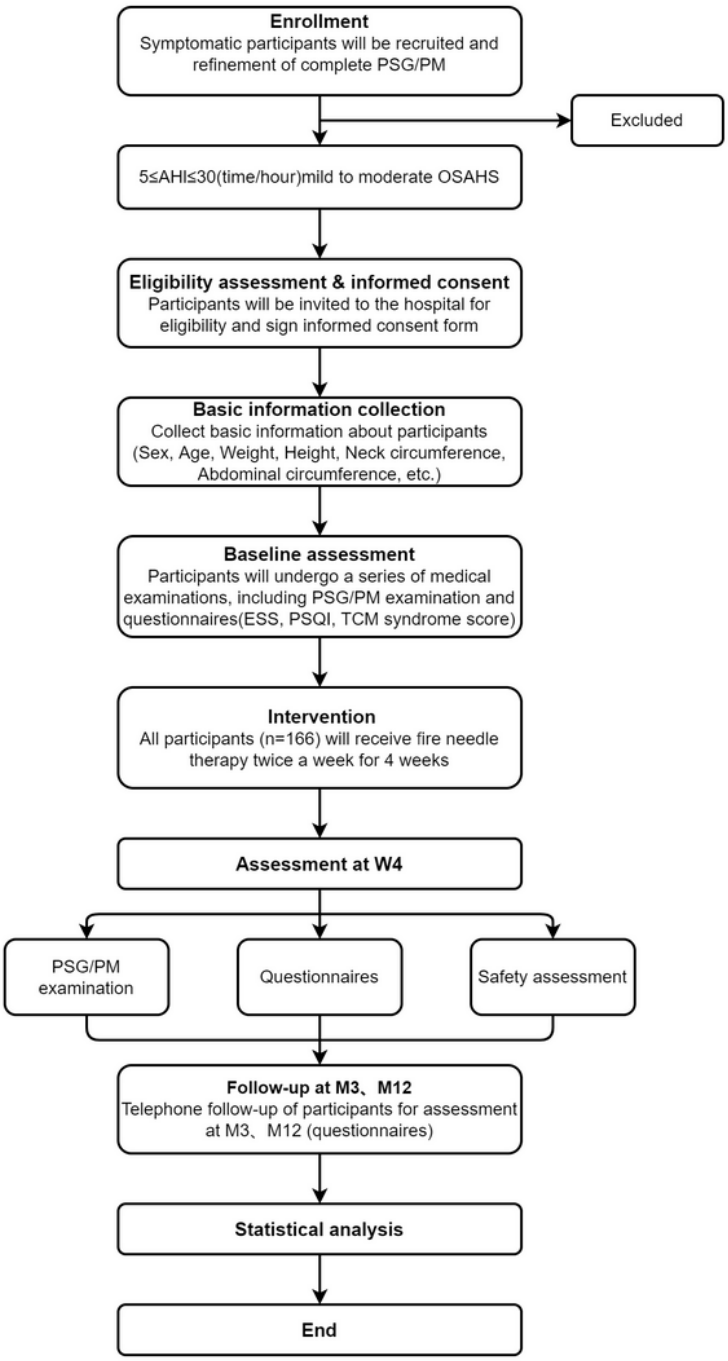
This study was approved by the Ethical Committee of the Beijing Hospital of Traditional Chinese Medicine on July 23rd, 2021(approval No.2021BL02-056-02).Informed consent will be obtained from all participants before study initiation.

References

1. Kapur V.K, Auckley D.H, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American academy of sleep medicine clinical practice guideline[J]. J Clin Sleep Med, 2017, 13(3): 479-504.
2. Morsy N.E, Farrag N.S, Zaki N.F.W, et al. Obstructive sleep apnea: personal, societal, public health, and legal implications. Rev Environ Health. 2019 Jun 26;34(2):153-169.
3. Senaratna C.V, Perret J.L, Lodge C.J, et al. Prevalence of obstructive sleep apnea in the general population: A systematic review. Sleep Med Rev. 2017 Aug;34:70-81.
4. Senaratna C.V, Perret J.L, Lowe A, et al. Detecting sleep apnoea syndrome in primary care with screening questionnaires and the Epworth sleepiness scale. Med J Aust. 2019 Jul;211(2):65-70.
5. Zhang H, Liang C.G, Tong T, et al. A qualitative study on the causes of delayed treatment in patients with obstructive sleep apnea hypopnea syndrome [J]. General Practice Nursing,2021,19(28):4003-4006.
6. Suzuki M. Obstructive sleep apnea -consideration of its pathogenesis. Auris Nasus Larynx. 2021 Nov 9:S0385-8146(21)00251-0.
7. Lyons O.D, Ryan C.M. Sleep Apnea and Stroke. Can J Cardiol. 2015 Jul;31(7):918-27.
8. Meschia J.F, Bushnell C, Boden-Albala B, et al; American Heart Association Stroke Council; Council on Cardiovascular and Stroke Nursing; Council on Clinical Cardiology; Council on Functional Genomics and Translational Biology; Council on Hypertension. Guidelines for the primary prevention of stroke: a statement for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2014 Dec;45(12):3754-832.
9. Young T, Palta M, Dempsey J, et al. The occurrence of sleep-disordered breathing among middle-aged adults. N Engl J Med. 1993 Apr 29;328(17):1230-5.
10. Arnardottir E.S, Bjornsdottir E, Olafsdottir K.A, et al. Obstructive sleep apnoea in the general population: highly prevalent but minimal symptoms. Eur Respir J. 2016 Jan;47(1):194-202.
11. Patil S.P, Ayappa I.A, Caples S.M, et al. Treatment of Adult Obstructive Sleep Apnea with Positive Airway Pressure: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2019 Feb 15;15(2):335-343.
12. Lin H.J, Yeh J.H, Hsieh M.T, Hsu C.Y. Continuous positive airway pressure with good adherence can reduce risk of stroke in patients with moderate to severe obstructive sleep apnea: An updated systematic review and meta-analysis. Sleep Med Rev. 2020 Dec; 54:101354.

13. Chen B, Zhang X.S, Huang H, et al. Comparative study of acupuncture and nCPAP in the treatment of OSAHS patients [J]. Chinese Acupuncture and Moxibustion,2008(02):79-83.
14. He Q.Y, Wang W.E. Guidelines for the Diagnosis and treatment of Obstructive Sleep apnea hypopnea syndrome (Primary edition)[J].Chinese Journal of Respiratory and Critical Care,2015,14(04):398-405.
15. Han M, Cao H.J, Zhang Y, et al. Single group test target value method and its application in the evaluation of non-drug therapy in traditional Chinese medicine[J].Beijing Traditional Chinese Medicine,2020,39(05):499-503.DOI:10.16025/j.1674-1307.2020.05.027.
16. Tang X.R, Huang Y.H, Wang Y, et al. Comparative study on sample size calculation method of single group target value test[J].Chinese Journal of Disease Control and Prevention,2013,17(11):993-996.

Figures



Flowchart of the proposed trial.OSAHS, Obstructive sleep apnea-hypopnea syndrome; PSG, Polysomnography;PM, Portable monitoring; ESS, Epworth sleepiness scale; PSQI, Pittsburgh sleep quality index; TCM, Traditional Chinese medicine.

Figure 1

Legend not included with this version

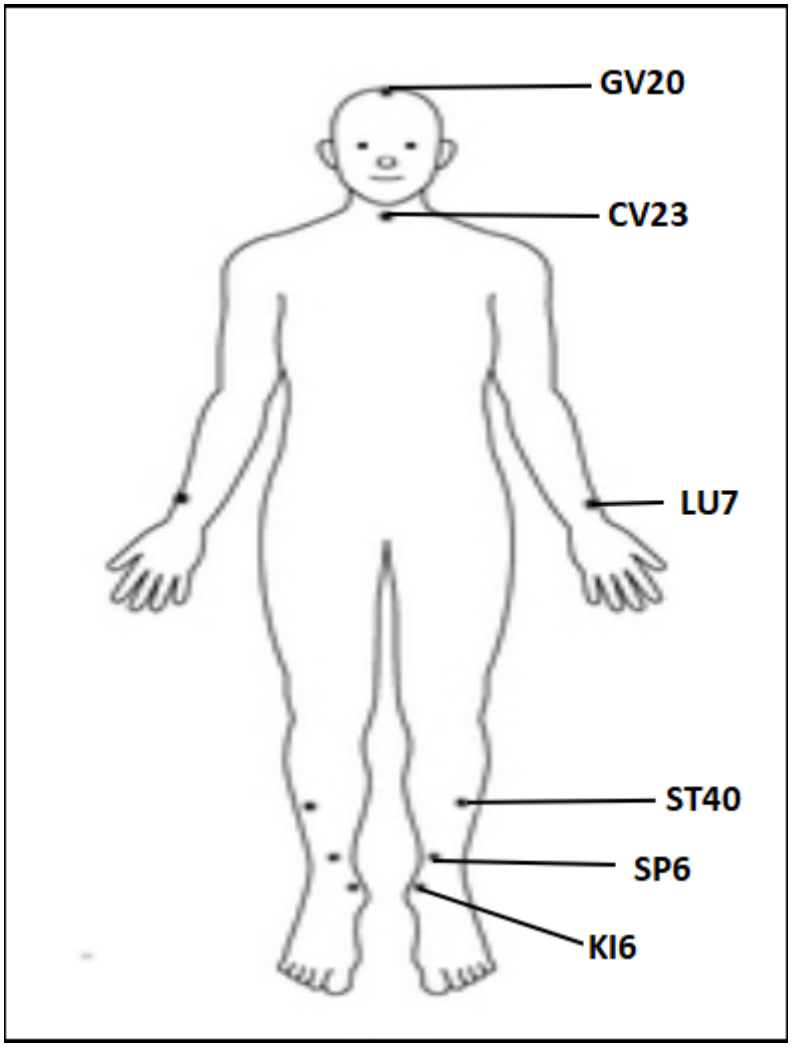


Figure 2

Legend not included with this version

Figure 3

Legend not included with this version

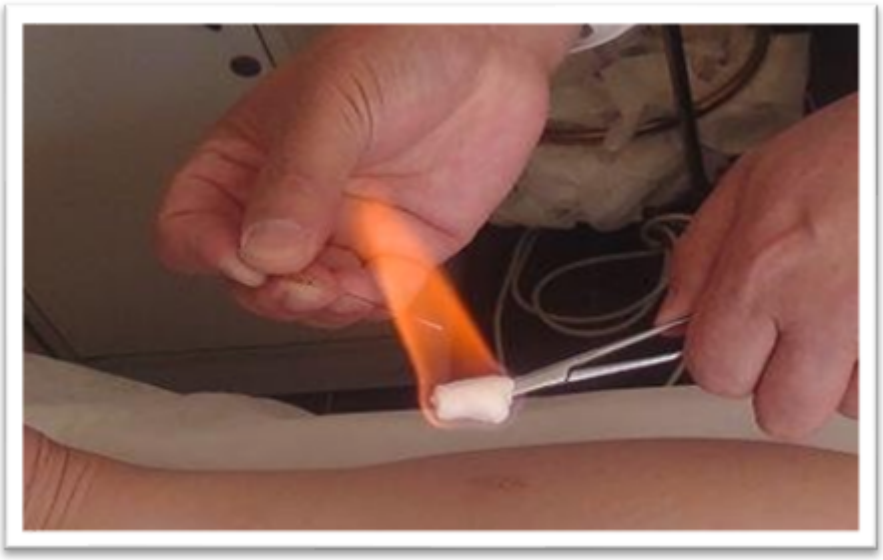


Figure 4

Legend not included with this version

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Appendix1.docx
- Appendix2.docx
- Appendix3.docx
- Appendix4.docx