ISRCTN10474528 https://doi.org/10.1186/ISRCTN10474528

Sedative and tranquilising acupuncture in the treatment of primary insomnia with anxiety

Submission date
22/05/2024

Recruitment status
No longer recruiting

Registration date
04/06/2024

Overall study status
Completed

Last Edited
04/06/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
This study aimed to compare the effectiveness of sedative and tranquilising acupuncture with that of conventional medicine in the treatment of primary insomnia with anxiety to provide a novel approach to the clinical treatment of this type of insomnia.

Who can participate?
Patients aged 18-65 years with primary insomnia with anxiety

What does the study involve?
Patients were randomly divided into a treatment group and a control group. The treatment group were treated with sedative and tranquilising acupuncture, and the control group were treated with estazolam, a conventional drug. Treatment effectiveness was determined after 4 and 8 weeks of treatment.

What are the possible benefits and risks of participating?
Sedative and tranquilising acupuncture can significantly improve sleep quality in patients with primary insomnia, and it can alleviate anxiety in these patients.

Where is the study run from?
Shunyi Hospital, Beijing Traditional Chinese Medicine Hospital (China)

When is the study starting and how long is it expected to run for?
January 2020 to March 2023

Who is funding the study?
1. Young Qihuang Scholars Cultivation Project (China)
2. National Traditional Chinese Medicine Innovation Backbone Talent Project (China)

Who is the main contact?
Peng Bai, baipeng_bp3147@163.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Clinical effects of sedative and tranquilising acupuncture in the treatment of primary insomnia with anxiety in different Traditional Chinese Medicine constitutions

Study objectives
Sedative and tranquilising acupuncture can significantly improve sleep quality and efficacy in patients with primary insomnia, and it can alleviate anxiety in these patients. Compared with the control group, the treatment group exhibited long-term efficacy.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/04/2020, Ethics Committee of Shunyi Hospital, Beijing Traditional Chinese Medicine Hospital (No. 1 Jiansheng Street, Shunyi District, Beijing, 100000, China; +86 (0) 1089413365; syzyjjxf2020@163.com), ref: 2020SYKY03-01

Study design
Single-centre double-blinded interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Patients with primary insomnia with anxiety

Interventions
A total of 113 patients who met the inclusion criteria were selected for this study using a convenience sampling method. The simple random sampling method was used to divide them into a treatment group using sedative and tranquilising acupuncture and a control group using estazolam, a conventional drug.

Acupuncture procedure:
Acupoint selection: Four Shencong, bilateral Shenmen and bilateral Sanyinjiao were the main acupoints.
Technique: The needle was inserted to a shallow depth at Four Shencong, to a medium depth at Shenmen and perpendicularly at Sanyinjiao. Once inserted, the needle was left for 30 minutes, with the lifting-and-thrusting method applied after every 10 minutes.
30 minutes each time, five times a week from Monday to Friday (rest on Saturday and Sunday). Ten treatments were taken as a course, and a total of two courses of treatment (4 weeks) were given.

Estazolam treatment (control group): estazolam 1 mg every night (Shandong Xinyi Pharmaceutical Co., LTD).

Efficacy was determined after 4 and 8 weeks of treatment. The statistical analysis was performed using SPSS 26.0 statistical software. The measurement data were expressed as mean ± standard deviation. Data conforming to a normal distribution were compared between the two groups using an independent sample t-test, and the within-group comparison was conducted using a paired sample t-test. Data not conforming to a normal distribution were compared using the Wilcoxon rank-sum test, and the count data were tested using a chi-square test. The difference was considered statistically significant at $P < 0.05$.

Intervention Type
Supplement

Primary outcome measure
Primary insomnia assessed using the Pittsburgh Sleep Quality Index (PSQI) after 4 and 8 weeks of treatment

Secondary outcome measures
1. Anxiety states assessed using the Self-Assessment Scale (SAS) after 4 and 8 weeks of treatment
2. Depressive states assessed using the Self-Rating Depression Scale (SDS) after 4 and 8 weeks of treatment

Overall study start date
01/01/2020

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1. Those who met the above diagnostic criteria of primary insomnia and anxiety state
2. Age between 18 and 65 years, with no restriction on gender
3. Those who have not taken other anti-insomnia and anxiety medication in the last month
4. Permission was obtained from the patient

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
120

Total final enrolment
113

Key exclusion criteria
1. Those who did not meet the above inclusion criteria
2. Age <18 or >65 years, and pregnant or lactating women
3. Individuals with combined visceral diseases, severe diseases of the immune and blood

systems, mental illnesses and recent neurological injuries such as traumatic brain injury or spinal cord injury
4. Skin infection at the acupoint area

Date of first enrolment
20/08/2020

Date of final enrolment
13/03/2023

Locations

Countries of recruitment
China

Study participating centre
Shunyi Hospital, Beijing Traditional Chinese Medicine Hospital
No. 1 Jiansheng Street
Shunyi District
Beijing
China
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Sponsor information

Organisation
Shunyi Hospital of Beijing Traditional Chinese Medicine Hospital

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.bjsyzy.com/

ROR
https://ror.org/01qq0qd43

Funder(s)

Funder type
Other

Funder Name
Young Qihuang Scholars Cultivation Project

Funder Name
National Traditional Chinese Medicine Innovation Backbone Talent Project

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/06/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Peng Bai (baipeng_bp3147@163.com).

IPD sharing plan summary
Available on request