

A study of acupuncture “Chou’s Tiaoshen” acupoints on patients in subacute insomnia

Submission date 01/12/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/12/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/03/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Insomnia is a common sleeping problem. Insomnia makes it hard to initiate or maintain sleep or nonrestorative sleep. Sleep disturbance causes distress or damage in social, occupational, or other important areas of functioning. As an alternative therapeutic method, acupuncture offers another option for insomnia. Acupuncture is a treatment that inserts fine needles at certain areas in the body to be therapeutic. It is based on the theory of meridians of Traditional Chinese Medicine (TCM). Meridian is considered to be a network of passages of the energy power, Qi. According to ancient TCM classic of Nei Jing (Inner Classic), insomnia is a consequence of the vicious cycle of “daytime low-spirit” and “nighttime hyperarousal state.” Acupuncture is considered to be beneficial to restore the normal sleep-wake cycle by regulating and restoring the natural flow of Qi. The aim of this study is to explore the effect of using acupuncture (and using specific Chou’s Tiaoshen acupoints) to help patients with insomnia.

Who can participate?

Adults aged 20-60 years old who have sleep difficulties at least three nights per week.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive acupuncture using the “Chou’s Tiaoshen” acupoints five times a week for two weeks. Those in the second group take estazolam 30 minutes prior to bedtime for two weeks. Participants are followed up to examine the quality of their sleep and their insomnia symptoms using sleep diaries and questionnaires before and after the treatment.

What are the possible benefits and risks of participating?

It is expected that participants will experience lower frequency and severity of subacute insomnia as well as improved sleep quality, thus improving life quality of patients and alleviating side effects of taking drugs and operations. Furthermore, data and evidence gained from this study will be helpful in the future research projects. The risks of taking part are minimal. Acupuncture is a very safe treatment when given by properly trained clinicians. Occasionally acupuncture can make people feel nauseous or faint or experience a temporary increase in pain either during or after treatment. Participants are warned of these potential side-effects before consenting to have acupuncture.

Where is the study run from?

Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University (China)

When is the study starting and how long is it expected to run for?

June 2017 to December 2018

Who is funding the study?

Beijing Municipal Administration of Hospitals (China)

Who is the main contact?

Dr Huanqin Li

Contact information

Type(s)

Scientific

Contact name

Ms Huanqin Li

Contact details

Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University

Backstreet Gallery No. 23

Dongcheng District

Beijing

China

100010

Type(s)

Public

Contact name

Miss Tuo Tuo

Contact details

Beijing University of Chinese Medicine

North Third Ring Road NO.11

Chaoyang District

Beijing

China

100029

+86 18001104650

tuotuo1123@icloud.com

Additional identifiers

Study information

Scientific Title

Observation on clinical efficacy of acupuncture "Chou's Tiaoshen" acupoints on patients in subacute insomnia

Study objectives

Compared with taking estazolam, acupuncture "Chou's Tiaoshen" acupoints can improve patients' sleeping quality in subacute insomnia equally or better.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethical Committee of Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University, 18/07/2017, ref:2017BL-055-01.

Study design

Interventional randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Subacute insomnia

Interventions

Participants are randomly allocated to one of two groups.

Treatment group: Participants receive acupuncture using "Chou's Tiaoshen" acupoints, including Baihui (GV-20), Shenting (GV-24), and Sishencong (EX-HN1), Sanyinjiao (SP-6), Shenmen (HT-7) . Using stainless steel needles (0.32×40 mm, HuaTuo, China). Then some other points like, Danzhong(CV-17), Taixi (KI-3), Qihai (CV-6), Taichong (LR3), and Qiuxu(GB-40) are chosen. Operation: Patients in supine position. Baihui (GV-20), Shenting (GV-24), and Sishencong (EX-HN1) are punctured at a depth of 20-25mm obliquely. Sanyinjiao (SP-6) and Shenmen (HT-7) are inserted 15mm perpendicularly. Until feeling tactile sensation then manually manipulated by rotation methods to produce a characteristic sensation known as "De Qi".

Mild reinforcing and attenuating, retaining the needle for 30minutes. When all the needles inserted, needle handles needs to be a line horizontally and vertically. The treatment will be given once a day and 5 times a week in weekdays, the course will last two weeks.

Control group: Participants take estazolam 30min prior to bedtime in the day. The course will last two weeks.

Participants keep sleep diaries and are followed up with questionnaires to examine thier symptoms of insomnia and sleep quality.

Intervention Type

Other

Primary outcome(s)

Sleep quality and disturbances are measured using the Pittsburgh sleep quality index (PSQI) at baseline, day 14 and day 28.

Key secondary outcome(s)

1. Insomnia severity level are measured using insomnia severity index (ISI) at baseline, day 14 and day 28
2. Daytime function or daytime fatigue is measured using Fatigue Scale (FS)(FS including the items of physical fatigue and mental fatigue) at baseline, day 14 and day 28
3. Symptoms of insomnia are measured using Sleep diaries. It will be recorded everyday after patients start to be treated, and we will take their Sleep diaries at day 14 and day 28

Completion date

30/03/2019

Eligibility

Key inclusion criteria

1. According to the Diagnostic and Statistical Manual of Mental Disorders Text Revision, 5th ed (DSM-V) and Chinese Adult Insomnia Diagnosis and Treatment Guide 2012
2. A predominant complaint of dissatisfaction with sleep quantity or quality, associated with one (or more) of the following symptoms:
 - 2.1. Difficulty initiating sleep
 - 2.2. Difficulty maintaining sleep, characterized by frequent awakenings or problems returning to sleep after awakenings
 - 2.3. Early-morning awakening with inability to return to sleep
3. The sleep disturbance causes clinically significant distress or impairment in social, occupational, educational, academic, behavioral, or other important areas of functioning
4. The sleep difficulty occurs at least 3 nights per week. The sleep difficulty is present for at least 1 months
5. Experienced insomnia between 4 weeks and 3 months before the start of project
6. Age: patients between 20 and 60 years old
7. Not yet taken estazolam for more than 3 days
8. Patients who agreed to participant in this trial and assigned the informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Having depression, anxiety or schizophrenia
2. Patients with serious heart, liver, kidney and hematopoietic system diseases or mental

disorders

3. Patients who could not cooperate with the investigators

4. Insomnia course less than 4 weeks

5. Taken anti-anxiety depression drugs or assisted sleeping medication in the past 6 months

Date of first enrolment

20/01/2018

Date of final enrolment

31/12/2018

Locations

Countries of recruitment

China

Study participating centre

Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University

Backstreet Gallery No. 23 in Dongcheng District

Beijing

China

100010

Sponsor information

Organisation

Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University

ROR

<https://ror.org/057vq6e26>

Funder(s)

Funder type

Government

Funder Name

Beijing Municipal Administration of Hospitals

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Ms Huanqin Li (hqin_li@163.com).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		26/03/2020	26/03/2020	No	No