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

Submission date
01/12/2017

Recruitment status
No longer recruiting

Registration date
13/12/2017

Overall study status
Completed

Last Edited
26/03/2020

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 maintainsleep 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Observation on clinical efficacy of acupuncturing “Chou’s Tiaoshen” acupoints on patients in subacute insomnia

Study objectives
Compared with taking estazolam, acupuncturing “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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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 incluing 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

Overall study start date
01/06/2017

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

Age group
Adult

Sex
Both

Target number of participants
96

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
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Sponsor information

Organisation

Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/057vq6e26

Funder(s)

Funder type
Government

Funder Name
Beijing Municipal Administration of Hospitals

Results and Publications

Publication and dissemination plan
We plan to publish a protocol of this trial in about 6-8 months after the registration, and one paper of the trial including results in a high-impact peer reviewed journal in one year after the trial.

Intention to publish date
01/08/2019

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